Peter D. Weinstein, Texas State Bar No. 24126484 Entralta P.L.L.C. 4500 Williams Dr. Ste 212, PMB 511 Georgetown, Texas 78633

Tel: (805) 444-7865 Fax: (805) 322-4469

Graigory B. Fancher Texas State Bar No. 24052016 Bourland, Wall & Wenzel, P.C. 301 Commerce Ste 2500 Fort Worth, Texas 76102 Tel: (817) 877-1088

Tel: (817) 877-1088 Fax: (817) 877-1636

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

HOUSTON

Jung-Hoon Yoon Case No. 4:22-cv-4089 Plaintiff, COMPLAINT FOR VIOLATION OF 42 CFR PART 93, THE FOURTEENTH AMENDMENT OF THE UNITED STATES VS. CONSTITUTION AND ARTICLE I. Nisha J. Garg, Carolee King, Daniel SECTION 19 OF THE TEXAS STATE Sharphorn, Ben Raimer, Charles P. Mouton, CONSTITUTION David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, Gracie Vargas, each an individual; and DOES 1 through 100, inclusive. Defendants.

1 The Parties 2 Plaintiff Dr. Jung-Hoon Yoon ("Plaintiff") complain of Defendants Nisha J. Garg, Carolee 3 King, Ben Raimer, Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio 4 Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebeca Wong, B. Monte 5 Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming 6 Tzeng, Shinji Makino, Gracie Vargas (each individually a "Defendant" and collectively, 7 "Defendants") as follows: 8 1. Plaintiff Dr. Joon Hoon Yoon ("Dr. Yoon") is an individual who resides in Houston, 9 Texas. Dr. Yoon is a Senior Scientist at the University of Texas Medical Branch in Galveston Texas 10 ("UTMB") where he has worked for seventeen (17) years in the laboratory of Dr. Louise Prakash and 11 Dr. Satya Prakash. 2. On information and belief, Defendant Nisha J. Garg is currently a Professor in the 12 13 Departments of Microbiology & Immunology and Pathology at UTMB and at the time her offenses 14 occurred was also the Scientific Integrity Officer at UTMB and resides in League City, Texas. 15 3. On information and belief, Carolee King is Senior Vice President and General Counsel 16 for UTMB and resides in Bellaire, Texas. 17 4. On information and belief, Ben Raimer at the time that the offenses occurred was the President of UTMB and resides in Galveston, Texas. 18 19 5. On information and belief, Charles P. Mouton is the President of UTMB and resides 20 in Galveston, Texas. 21 6. On information and belief, Daniel Sharphorn is the Vice Chancellor and General 22 Counsel for the University of Texas System Office of General Counsel and resides in Austin, Texas. 23 7. On information and belief, David Niesel at the time his offenses occurred was the 24 Scientific Integrity Officer of UTMB and resides in Georgetown, Texas. 25 8. On information and belief, Rohan Hebbar is the Assistant Vice President of Legal 26 Affairs at UTMB and resides in Houston, Texas.

1 9. On information and belief, Anthony Okorodudu is the current Scientific Integrity 2 Officer at UTMB and resides in Frisco, Texas. 3 10. On information and belief, Giulio Taglialatela is the Vice Chair for Research for the 4 Department of Neurology and the Director of the UTMB Mitchell Center for Neurodegenerative 5 Diseases and resides in Dickinson, Texas. 6 11. On information and belief, David H. Walker is a Professor in the Department of 7 Pathology at UTMB and resides in Corpus Christi, Texas. 8 12. On information and belief, Lorraine Evangelista is a Professor and Associate Dean for 9 Research and Scholarship at UTMB and resides in Mesquite, Texas. 10 13. On information and belief, Blake Rasmussen was a Professor in the School of Health 11 Professions and is currently a Professor in the Department of Biochemistry and Molecular Biology at 12 UTMB and resides in League City, Texas. 13 14. On information and belief, Rebecca Wong is a Professor in the Department of 14 Population Health and Health Disparities at UTMB and resides in League City, Texas. 15 15. On information and belief, B. Monte Pettitt is a Professor in the Department of 16 Biochemistry and Molecular Biology at UTMB and resides in Houston, Texas. 17 16. On information and belief, V. Suzanne Klimberg is a Professor and the Division Chief 18 of Surgical Oncology and Colorectal Surgery in the Department of Surgery at UTMB and resides in 19 Galveston, Texas. 20 On information and belief, William Calhoun is the Vice Chair for Research at UTMB 17. 21 and resides in Houston, Texas. 22 18. On information and belief, Mahmoud Ahmed is Professor in the Department of 23 Obstetrics and Gynecology at UTMB and resides in Houston, Texas. 24 19. On information and belief, Michael Kinsky is Vice Chair for Research at UTMB and resides in League City, Texas. 25 26 20. On information and belief, Huey-Ming Tzeng is Professor in the School of Nursing at

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UTMB and resides in Galveston, Texas.

- 21. On information and belief, Shinji Makino is a Professor in the Department of Microbiology & Immunology at UTMB and resides in Galveston, Texas.
- 22. On information and belief, Gracie Vargas is a Professor in the Department of Neurobiology at UTMB and resides in Galveston, Texas.

Venue

- 23. This is an action for a violation of federal law and due process rights of Plaintiff Jung-Hoon Yoon by Defendants under the United States Code of Federal Regulations ("CFR"), the Texas State Constitution and the United States Code ("USC"). More particularly, this action is for violation of 42 CFR part 93, the fourteenth amendment of the United States Constitution and Article I, Section 19 of the Texas Constitution and under 42 U.S.C. § 1983. This Court has jurisdiction over the subject matter of this Complaint under 28 U.S.C. §§ 1331 and 1338(a).
- 24. Personal Jurisdiction over the Defendants is proper in this Court in that this is a judicial district in which one or more Defendants reside and all Defendants are residents of the State of Texas. Venue in this judicial district is proper under 28 U.S.C. §§ 1391(b), (c).

STATEMENT OF FACTS

I. Summary of the Allegations

- 25. This case regards a false allegation of scientific misconduct against Plaintiff Jung-Hoon Yoon ("Dr. Yoon") that was made by a former co-worker who had a misplaced grudge against Dr. Yoon. This case further regards a group of Defendants, all of whom are employed by the University of Texas, with most employed by the University of Texas Medical Branch in Galveston, Texas ("UTMB") who took the false allegation and then ran with it over a period of now more than three (3) years to torture, harm, damage, crucify and just take inhuman actions against Dr. Yoon through their unremitting failure to follow simple procedures and processes as set forth under federal law (42 CFR part 93) and UTMB's internal procedures and policies as set forth in its Policy and Procedure Manual on Integrity of Research ("PPMIR"). (42 CRP part 93 attached hereto as Exhibit A; the UTMB PPMIR attached hereto as Exhibit B).
- 26. 42 CFR part 93 and the UTMB PPMIR sets forth the procedures for looking into an allegation of scientific misconduct (also called "research misconduct"). The procedures are simple

and easy to follow. Despite this, each and every Defendant at every turn during a period of now more than three (3) years have violated the simple procedures. Defendants took these illegal actions despite being told by Dr. Yoon and his legal counsel in writing over and over and over during the last more than three (3) years that Defendants were breaking the law and violating the procedures set forth in UTMB's PPMIR. Dr. Yoon and his legal counsel kept telling Defendants in writing that they were violating Dr. Yoon's due process rights and that Defendants actions were causing Dr. Yoon great harm and damage to his mental, emotional and physical health. Indeed, as a result of Defendants' illegal actions, Dr. Yoon has suffered severe gastrointestinal issues, sleeplessness, recurring bouts of depression, marital issues and those closest to him have worried about his committing suicide during the most severe bouts of depression caused by Defendants illegal actions. Particularly, while waiting for Dr. Yoon to be terminated and his reputation ruined for a false allegation that was made for what in the end was no more than an honest mistake. In fact, it is a testament to Dr. Yoon that he has not taken his life after such inhumane treatment for more than three (3) years by Defendants.

- 27. With regard to those simple procedures, there are two main steps that Defendants have to follow. The first is an inquiry to determine if there is any merit to the allegation of scientific misconduct. If an allegation is considered to have merit based on sufficient evidence to support a claim of scientific misconduct, then and only then, does an investigation begin. For both the inquiry and the investigation there are simple and easily understandable written procedures on what is to be done and what has to be included in a written report. There is also a clear and concise definition of what constitutes scientific misconduct and fraud and what constitutes an honest mistake. There is also a well-defined timeline for completion of the inquiry. This timeline requires that an inquiry be completed in no more than sixty (60) days and the investigation to be completed in no more than one-hundred and twenty (120) days.
- 28. Despite the simple written procedures set forth in the federal law and the PPMIR, and the clear definition of what constitutes scientific misconduct and what does not, Defendants have failed again and again and again to follow them. Defendants have also failed to provide even one iota of evidence to provide support for an allegation of scientific misconduct or fraud by Dr. Yoon that would satisfy the requirements for such a claim under 42 CFR part 93 and the UTMB PPMIR. Instead,

all Defendants have shown again and again and again is that at worst, Dr. Yoon was careless in making an honest mistake. But truth and honesty have never been hallmarks of any of the Defendants' during the over three (3) years of endless illegal inquiries and investigations. Thus, through this complaint and this lawsuit, Dr. Yoon hopes to receive justice against each and every Defendant for their illegal actions.

II. The Easily Understandable Procedure for an Investigation

a. The General Rules and Definitions

- 29. 42 CFR part 93 is the federal law that sets forth in simple language the procedures and processes that are to be followed following receipt of an allegation of scientific misconduct. The UTMB PPMIR sets forth the procedures and processes employees at UTMB are to follow following receipt of an allegation of scientific misconduct. Both the federal law and UTMB PPMIR provide guidance that is easily understood on how to run an inquiry and if necessary, an investigation. To show how simple the procedures and processes set forth in 42 CFR part 93 and the UTMB PPMIR are, the sections most relevant to the present action are set forth below, starting with the general policy and relevant definitions of scientific misconduct.
- 30. First, the "General responsibilities for compliance" are set forth in 42 CFR §93.300. Under this part, the federal law requires:
 - a. That UTMB have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part, which UTMB accomplished with its policies and procedures set forth in its PPMIR; and,
 - b. That UTMB respond to each allegation in a "thorough, competent, objective and fair manner." As disclosed in the Statement of Facts set forth below, all of the Defendants failed and continue to fail to meet this requirement under the federal law. In the conduct of their actions as set forth below, it is abundantly clear that each Defendant was (i) not thorough; (ii) not competent in carrying out their illegal actions; (iii) never objective; and (iv) at no time fair to Plaintiff Dr. Yoon.

1	31. What constitutes scientific misconduct is defined in 42 CFR § 93.103 as the
2	"fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in
3	reporting research results."
4	(a) "Fabrication is making up data or results and recording or reporting them."
5	(b) "Falsification is manipulating research materials, equipment, or processes, or changing or
6	omitting data or results such that the research is not accurately represented in the research
7	record."
8	(c) "Plagiarism is the appropriation of another person's ideas, processes, results, or words
9	without giving appropriate credit."
10	(d) "Research misconduct does not include honest error or differences of opinion."
11	32. Further, based on the aforementioned definition of research misconduct, 42 CFR
12	§93.104 sets forth what is required for a finding of scientific misconduct. More particularly, scientific
13	misconduct requires that:
14	(a) "There be a significant departure from accepted practices of the
15	relevant research community; and
16	(b) The misconduct be committed intentionally, knowingly, or recklessly; and
17	(c) The allegation be proven by a preponderance of the evidence." (emphasis added).
18	33. According to the Merriam-Webster online dictionary, "intentionally" means (i) "a
19	usually clearly formulated or planned intention: Aim," (ii) "the act or fact of intending: purpose." (iii)
20	"directed with strained or eager intention: concentrated," or (iv) "having the mind, attention, or will
21	concentrated on something or some end or purpose." (www.merriam-webster.com/dictionary/intent).
22	34. According to the Merriam-Webster online dictionary, "knowingly" means (i)
23	"deliberately."
24	35. According to the Merriam-Webster online dictionary, "recklessly" means to be (i)
25	"marked by lack of proper caution: careless of circumstances" and (ii) "irresponsible."
26	(www.merriam-webster.com/dictionary/reckless).

1	36. The definition of scientific misconduct is reiterated by the UTMB Policy and
2	Procedure Manual on Integrity in Research ("PPMIR"), where Misconduct/Fraud in research is
3	defined as:
4	"fabrication, falsification, plagiarism, or other practices that materially deviate from those
5	that are commonly accepted within the academic community for proposing, conducting, or
6	reporting research. It does not include honest errors or honest differences in interpretations or
7	judgments of data." (emphasis added)
8	b. The Institutional Inquiry
9	37. According to 42 CFR part 93, before an investigation is to occur, an inquiry has to be
10	conducted to determine if there is sufficient evidence to support an allegation of scientific misconduct.
11	42 CFR §93.307 is the section that sets forth the legal requirements of an inquiry.
12	38. The parts of this section that are relevant to the present action are:
13	a. 42 CFR §93.307(a)(1), "An inquiry is warranted if the allegation – (1) Falls
14	within the definition of research misconduct under this part." (See also, PPMIR
15	Section V(A) – Assessment of Allegations)
16	b. 42 CFR §93.307(d) sets forth the "Criteria warranting an investigation."
17	i. 42 CFR §93.307(d)(1) requires that an "investigation is warranted if
18	there is – A reasonable basis for concluding that the allegation falls
19	within the definition of research misconduct under this part."
20	ii. 42 CFR §93.307(d)(2) requires that "Preliminary information-
21	gathering and preliminary fact-finding from the inquiry indicates that
22	the allegation may have substance."
23	c. 42 CFR § 93.307(e) states that an inquiry report is to be prepared that meets
24	all of the requirements set forth under 42 § 93.307. (See also, PPMIR Section
25	VI – The Inquiry Report)
26	d. 42 CFR § 93.307(f) requires that Dr. Yoon be provided "an opportunity to
27	review and comment on the inquiry report and attach any comments received
28	to the report." (See also, PPMIR Section VI(A)(9)
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1	e. 42 CFR § 93.307(g) sets forth that the SIO and the inquiry committee "must
2	complete the inquiry within 60 calendar days of its initiation unless
3	circumstances clearly warrant a longer period. If the inquiry takes longer than
4	60 days to complete, the inquiry record must include documentation of the
5	reasons for exceeding the 60-day period." (emphasis added) (See also, PPMIR
6	Section $V(G)$ – Time for Completion).
7	c. The Institutional Investigation
8	36. If and only if through the aforementioned inquiry evidence is found to support an
9	allegation of scientific misconduct, then and only then can an investigation can be initiated. 42 CFR
10	§ 93.310 is the section that sets forth the legal requirements of an investigation.
11	a. The relevant parts to this section that are relevant to the present action are:
12	i. 42 CFR § 93.310(f) requires that Defendants "Take reasonable steps
13	to ensure an impartial and unbiased investigation to the maximum
14	extent practicable, including participation of persons with
15	appropriate scientific expertise who do not have unresolved personal,
16	professional, or financial conflicts of interest with those involved
17	with the inquiry or investigation." (See also, PPMIR Section VII(E))
18	ii. 42 CFR § 93.310(g) requires that Defendants "Interview each
19	respondent, complainant, and any other person who has reasonably
20	identified as having information regarding any relevant aspects of the
21	investigation"(See also, PPMIR Section VII(E))
22	iii. 42 CFR § 93.310(h) requires that Defendants "Pursue diligently all
23	significant issues and leads discovered that are determined relevant
24	to the investigation, including any evidence of additional instances of
25	possible research misconduct, and continue the investigation to
26	completion." (See also, PPMIR Section VII(E))
27	37. 42 CFR § 93.312 is the section that sets forth the requirement that the investigation
28	committee must allow respondent Dr. Yoon to comment on an investigation report.

1 a. The relevant parts to this section that are relevant to the present action are: 2 i. 42 CFR § 93.312(a) requires that "The institution must give the 3 respondent a copy of the draft investigation report and, concurrently, 4 a copy of, or supervised access to, the evidence on which the report 5 is based. The comments of the respondent on the draft report, if any, 6 must be submitted within 30 days of the date on which the respondent 7 received the draft investigation report. (See also, PPMIR Section 8 VIII(B)(1)9 38. As is plainly clear from the recitation set forth above, the identified sections of 42 CFR part 93 are simple to understand and therefore, should have been easy to follow. Instead, as is set 10 11 forth in great detail below, each of Defendants Nisha J. Garg, Carolee King, Ben Raimer, Charles P. 12 Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H. Walker, 13 Lorraine Evangelista, Blake Rasmussen, Rebeca Wong, B. Monte Pettitt, V. Suzanne Klimberg, 14 William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, Gracie 15 Vargas have violated at least one, and in most instances, multiple sections of 42 CFR part 93. In doing 16 so, each of the Defendants has also violated the fourteenth amendment of the United States 17 Constitution and Article I, Section 19 of the Texas Constitution. 18 39. Similarly, as is also plainly clear from the citations to the UTMB PPMIR set forth 19 above, the identified sections of the UTMB PPMIR are simple to understand and therefore, should 20 have been easy to follow. Instead as is set forth in great detail below, each of Defendants Nisha J. 21 Garg, Carolee King, Ben Raimer, Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony 22 Okorodudu, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebeca 23 Wong, B. Monte Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, 24 Huey-Ming Tzeng, Shinji Makino, Gracie Vargas have violated at least one, and in most instances, 25 multiple sections of the UTMB PPMIR. 26 III. Defendants Begin the First Illegal Investigation 27 a. Defendant Garg Breaks the Law Right at the Start

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- 41. What is clear is that Dr. Yoon's honest mistake did not and does not constitute scientific misconduct or fraud. However, that has not mattered to the Defendants and continues to not matter. Instead, Defendants from the start have embarked on an over three-year odyssey where Dr. Yoon, the victim of their illegal actions, has had to suffer and suffer and suffer and continues to suffer to the present day for merely making an honest mistake.
- 42. This whole process started with a disgruntled co-worker, Jeseong Park ("Park"). Park filed a complaint on April 30, 2019, with Defendant Garg, who at that time was the Scientific Integrity Officer ("SIO") of UTMB. As will be set forth below, based on her illegal actions and absolute incompetence in handling the meritless complaint against Dr. Yoon, Defendant Garg was summarily terminated from the SIO position in October 2021.
- 43. In the complaint made to Defendant Garg, Park, who worked in the same laboratory as Dr. Yoon at UTMB, made several allegations and factual statements that were false. They were a bunch of lies based on the submission of false information to Defendant Garg. Thus, and ironically in making his claim, Park committed fraud by submitting false data to support his false allegation. However, in the end it did not matter as he had a willing accomplice in Defendant Garg.
- 44. Defendant Garg, without trying to determine the veracity of Park's statements in his complaint, instead embarked on an over two-year adventure comprising one illegal action after another (for which the other Defendants have also partaken, aided and abetted at one point or another since April 2019 and continuing to the present). These illegal actions, which can be described by no other words than malicious, inhumane, and callous, have greatly affected Dr. Yoon's health, mental and emotional state as well as fomenting professional damages that continue to this day and will continue for as long as the Defendants' illegal enterprise is allowed to operate.
- 45. Upon receiving a complaint alleging scientific misconduct, as stated above, there are very specific procedures that have to be followed pursuant to 42 CFR part 93 and UTMB's own

- PPMIR. In fact, Defendant Garg and the other Defendants, all of whom work at or worked at UTMB were and are charged with knowing the requirements and procedures set forth in the UTMB PPMIR. Similarly, all the Defendants as active participants in the illegal enterprise since April 2019 are charged in their roles during the various illegal sham inquiries and sham investigation to know the federal law regarding the federal legal requirements and procedures for conducting a scientific misconduct investigation. Despite Defendants' legal obligations, each and every one of them failed miserably and violated Dr. Yoon's civil and due process rights through their willful and wanton actions as is set forth below.
- 46. For reasons unknown to Dr. Yoon, despite receiving the factually flawed complaint in April 2019, Defendant Garg did not reach out to him about the allegations for almost five (5) months. Dr. Yoon first learned of the allegation following Defendant Garg's notice of Park's factually flawed complaint on September 16, 2019. (Defendant Garg letter attached as Exhibit C). With this letter, Defendant Garg was providing Dr. Yoon with notice that an inquiry was being initiated, which then legally required Defendant Garg and the other Defendants involved to follow a very specific and time limited procedure pursuant to 42 CFR part 93 and the UTMB PPMIR. Not surprisingly, all Defendants failed to do what was legally required of them.
- 47. For instance, in 42 CFR § 93.900(b), Defendant Garg was required to ensure to carry out the inquiry in a competent, objective, and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the scientific misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent or witnesses. Not surprisingly, Defendant Garg and the other Defendants violated this federal law. For instance, a simple investigation of the original factually flawed complaint by Park against Dr. Yoon would have determined that Park indeed had "unresolved personal" and "professional" conflicts with Dr. Yoon. Further, Defendant Garg failed to allow Dr. Yoon to approve or disapprove of those Defendants that Defendant Garg would include in her illegal scientific investigation committee in December 2019 in violation of federal law and the UTMB PPMIR.
- 48. In his complaint dated April 30, 2019, Park makes several claims that are difficult to reconcile with the truth. These include his claims that:

"I have decided my resignation because of the fraud."

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"I lost my confidence on our research anymore. That's the reason I made my mind to leave." (Exhibit SS attached hereto).

- 49. The reality that Defendant Garg would have learned if she had done even a modicum of inquiry into Park is that he contrived the allegations in his complaint only after he learned that he was not to be included as an author of the Genes & Development paper that includes the figure (hereinafter "Figure S2") that is alleged in the complaint by Park to be incorrect. (Yoon, J.H., Johnson, R.E., Prakash, L. & Prakash, S. (2019) DNA polymerase of accomplishes translesion synthesis opposite 1, N6-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33(6), 282 – 287.) (Genes & Development paper attached hereto as Exhibit D). It is reasonable to conclude that if Park had been an author on the Genes & Development paper, Park would never have filed his complaint. Moreover, Park was also upset that he was listed as the third author of a paper published in the Spring of 2019 in the journal Cell, instead of being listed as the second author that he believed he deserved. Park blamed Dr. Yoon for these alleged slights. Park believed that Dr. Yoon did not fight for him to get the authorship Park believed he deserved on the Genes & Development paper and as the second author on the Cell paper. This animosity toward Dr. Yoon festered and manifested and resulted in the factually flawed complaint filed against Dr. Yoon. However, in violation of the law, Defendant Garg failed to even inquire into Park's known and easily discoverable bias and hatred of Dr. Yoon. Nor have the other Defendants ever made such an inquiry in violation of 42 CFR § 93.900(b).
- 50. Now, what was alleged by Park in his factually flawed complaint was that the original published Supplemental Figure S2 included results that were from other experiments. In making his allegation, Park identified in his factually flawed complaint the results he alleged were the correct ones. However, and a bit ironically, when the results identified by Park to support his allegation of scientific fraud were reviewed, it was readily apparent that it was Park that submitted false information. The results Park identified as the alleged correct ones, turned out not to be those used in the original published Figure S2. Thus, Park made his allegation based on false information that he provided in his complaint. As Dr. Yoon proved to Defendant Niesel, Defendant Garg's replacement

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as Scientific Integrity Officer after she was fired, it only took a few minutes to show that the results were not the same. In the end, the allegations against Dr. Yoon by Park were put forth based on fraudulent results that were easily identifiable. However, at no time have any of the Defendants shown any interest in getting to the truth of the allegations by Park. Indeed, after being made aware of the falsity of the results provided by Park in his complaint, Defendants have continued to ignore this salient fact and plow ahead with their illegal actions against Dr. Yoon.

b. Dr. Yoon Proactively Publishes an Apology of His Honest Mistake

51. Not surprisingly, upon learning of the allegations made against him by Park, Dr. Yoon was incredibly distressed as he had taken great care during his career to perform his work at the highest level and with the greatest integrity. In fact, up until Park's complaint, Dr. Yoon had been considered a distinguished scientist with a stellar career and reputation. Thus, it was not surprising that upon notification by Defendant Garg of the allegation made against him by Park, Dr. Yoon's first reaction after realizing he had made an honest mistake, was to immediately and personally rerun the experiments to regenerate the data from the original published Figure S2. This work was conducted under the watchful eyes of the scientists within whose laboratory he worked – Dr. Louise Prakash and Dr. Satya Prakash. Dr. Yoon conducted these experiments starting in September 2019 and put together a new Supplemental Figures S2 that was promptly submitted to the journal in which the paper was published – Genes & Development. The new Figure S2 was published as a corrigendum. By publishing the corrigendum, Dr. Yoon publicly admitted his honest mistake to the readers of the scientific journal within which the original Figure S2 was published. Dr. Yoon completed the experiments used to create the corrigendum Figure S2 by early November 2019. Dr. Louise Prakash, in her role as the corresponding author, submitted the new Figure S2 as part of the corrigendum on November 14, 2019, to Genes & Development. It is important to note that as with the original Figure S2, the corrigendum Figure S2 was not substantive to, and did not affect, the conclusions and findings of the Genes & Development paper. While it was nice to have this figure in the published paper, it was not a necessary figure to include in the paper.

52. Prior to submission of the corrigendum on November 14, Dr. Louise Prakash had corresponded with Laureen Connell, editor for Genes & Development. This correspondence was sent to alert Genes & Development of the honest mistake that had occurred and that a corrigendum would be filed. During this correspondence, Dr. Louise Prakash admitted that:

"Dr. Jung-Hoon Yoon, the first author of the paper, who had compiled the western blots for the original Supplemental Figure S2, did not keep a record of western blots used for assembling each segment of Supplemental Figure S2. Hence, we were unable to confirm that the western blots were assembled correctly. Because of our concern about the accuracy the data in Supplemental Figure S2, we asked Dr. Yoon to carry out an entirely new set of experiments so that the accuracy of each step could be unambiguously verified. We have followed this work closely and have gone over the entire set of western blot data carefully; we are confident of its accuracy." (Email dated 10/24/2019 attached as Exhibit XX).

As would become apparent throughout the whole process over the last three (3) years, Dr. Yoon was open and honest that he made a mistake and that he was careless in preparing the original published Figure S2. Based on the public admission and submission of the corrigendum, this alone should have ended this whole matter at the start. As is laid out below, at no time have any of the Defendants given Dr. Yoon credit for publicly admitting his mistake. Instead, all of the Defendants jointly and in their individual capacity have led a merciless crusade in an inhumane manner to torture and cause and have caused great harm and damage to Dr. Yoon.

53. Prior to publication of the corrigendum, questions were asked about Figure S2. After receiving reasonable answers for what had occurred, Genes & Development published the new Figure S2 as a corrigendum on January 1, 2020. (Corrigendum attached as Exhibit E). This should have been the end of the matter, but unfortunately, Defendants could not get out of their own way. In particular, Defendant Garg was going to get her pound of flesh and continue to proceed with her illegal investigation that was aided and abetted at this time by Defendants Carolee King, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne Klimberg. Each of these additional Defendants were members of the ill-fated scientific investigation committee of December 2019.

54. Now, in publishing the new Figure S2 as a corrigendum, Dr. Louise Prakash, as corresponding author of the paper, provided an explanation that was published on behalf of the authors as part of the corrigendum regarding Dr. Yoon's honest mistake. The corrigendum included the following statement:

"In Supplemental Fig. S2 in the above article, we have been unable to confirm that the Western blots in panels A-C were assembled correctly. Because of our concerns about the accuracy of the data in the Western blots, we are presenting a new set of verified experiments in the new Supplemental Fig. S2, which can be found in the Revised Supplemental Material online. This change in no way affects any of the results or conclusions of this study. The authors apologize for this error" (Exhibit E attached hereto)

- 55. With this one statement, Dr. Yoon had cleared the air and told the scientists who read Genes & Development who would have seen the publication with the original published Figure S2 all the relevant facts about what had occurred. In particular, the honest mistake, even if not corrected, in no way affected the results or conclusions of the published paper. This should have ended the whole matter. But with Defendant Garg and the Defendants comprising the scientific investigation committee of December 2019, this was too much fun. Damn the law and UTMB's official printed policies. They were going to make a name for themselves and get their pound of Dr. Yoon's flesh. The truth was to be damned no matter how many federal laws they would break.
- 56. Ironically, Genes & Development was sufficiently satisfied with the corrigendum and the explanation of the honest mistake that the journal published another paper with Dr. Yoon as the first author. This paper titled "Implications of inhibition of Rev1 interaction with Y family DNA polymerases for cisplatin chemotherapy" was published in the September 1, 2021, issue of Genes and development. What is ironic is that Genes & Development was so impressed with this paper that they asked if it was ok for the journal to get in touch with UTMB:

"regarding publicity efforts for your G&D manuscript. We are optimistic that general media outlets &/or other scientific journals – such as Science, Nature, Nature Reviews – might be interested in covering this. To facilitate this, we would like to get in touch with the media affairs contact at your institution to see if/what publicity efforts they

have planned for your upcoming paper." (Email dated 7/19/2021 attached as Exhibit YY).

Not surprisingly, UTMB did not respond to the request from Genes & Development, and the paper was not publicized.

C. Defendants Ignore Dr. Yoon's Letter and Continue Their Illegal Actions

- 57. So, Defendant Garg continued her illegal actions and plowed ahead violating one federal law after another. For a bonus, Defendant Garg also violated one UTMB PPMIR policy after another. For instance, Defendant Garg failed to abide by the legal requirements set forth in 42 CFR § 93.307(e), 42 CFR § 93.307(f) and 42 CFR § 93.307(g). More particularly, defendant Garg failed to provide Dr. Yoon the opportunity to comment on the alleged allegations in the complaint made against him. Such an opportunity would have taken the form of a formal interview or other means for Dr. Yoon to answer any questions raised against him. It would also have provided Dr. Yoon the opportunity to provide a written response to any inquiry report. This latter failure by Defendant Garg of course was compounded by the fact that Defendant Garg actually never established a scientific inquiry committee in December 2019, who would have prepared such a report. Instead, Defendant Garg skipped over the legal requirement for an inquiry to take place and went straight to the investigation. In taking this step, Defendant Garg also failed to obtain Defendant President Raimer's legally required approval to even start of an investigation as required by the UTMB PPMIR.
- 58. About two months after the start of Defendant Garg's illegal inquiry, November 2019, Dr. Yoon had become desperate to get his voice out. Knowing that Defendant Garg would never let him have a chance to speak and provide exculpatory evidence to prove his innocence, Dr. Yoon sent Defendant Garg a letter on November 13, 2019. (Dr. Yoon 11/13/2019 letter attached as Exhibit F). As stated, Dr. Yoon sent this letter because in almost two months, Defendant Garg had made no real effort to contact Dr. Yoon to learn the true story behind the allegations. In his letter, Dr. Yoon clearly set forth the reasonable explanation for what occurred. In essence, Dr. Yoon stated that he was working on multiple projects at the same time and was under great time pressure. As a result of the time pressure, Dr. Yoon admitted that he had made a mistake by failing to record the location from which he took the results he used to create the originally published Figure S2. Basically, Dr. Yoon

was careless and made an honest mistake, one that he had not made before as this was an extraordinary situation. In providing his explanation, it is clear that Dr. Yoon did not commit scientific misconduct.

59. In this same letter, Dr. Yoon made Defendant Garg aware that in collaboration with Dr. Louise Prakash, new procedures had been created to ensure that the same mistake could not happen again. Dr. Yoon has followed these new procedures ever since. Not surprisingly. Defendant Garg could care less for the truth or those steps to prevent this honest mistake from happening again. Defendant Garg was going to get her pound of flesh and be a hero by showing that she could catch people in alleged bad acts, whether they were actually guilty or not. Of course, Defendant Garg could not have done this without the aid and abetting of Defendant General Counsel Carolee King, Defendant President Raimer, who was President of UTMB at that time and the Defendants on the December 2019 scientific inquiry committee. Particularly, as all of them were charged with knowing the simple-to-understand policies and procedures they were to follow under the UTMB PPMIR and the requirements of the federal laws under 42 CFR part 93.

60. Dr. Louise Prakash and Dr. Satya Prakash, within whose laboratory Dr. Yoon worked, also submitted letters to Defendant Garg on November 13, 2019, and November 5, 2019, respectively. (Dr. L. Prakash letter attached as Exhibit G and Dr. S. Prakash letter attached as Exhibit H). In their respective letters. Dr. Louise Prakash and Dr. Satya Prakash spoke of Dr. Yoon's long period of time working in their laboratory and the superlative work that he had conducted. They both also spoke of the incredible pressure Dr. Yoon was under during the time he prepared the originally published Figure S2 and how steps had been taken to ensure that a similar honest mistake could not occur again in their laboratory. Moreover, they discussed the nonconsequential nature of the originally published Figure S2. What that means is that this figure did not impact the scientific results or conclusions made in the Genes & Development paper. The results and conclusions were fully supported by all the other data and figures included in the Genes & Development paper. Finally, each stated that they believed that Dr. Yoon's mistake was an honest one. However, the truth did not matter to Defendant Garg. Nor did Defendant Garg care about the steps taken to ensure that Dr. Yoon's honest mistake did not occur again. Defendant Garg plowed on. She continued to break more federal laws and UTMB procedures.

d. Initiation of First Illegal Investigation

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- 61. Not only was Defendant Garg failing to follow through with each step of the inquiry process as required by law, she also was failing to complete the inquiry process within the statutory sixty (60) days-time limit. Under federal law and UTMB's PPMIR, Defendant Garg had to complete the inquiry by no later than November 17, 2019 and if relevant, by that date, notify Dr. Yoon that an investigation was to be initiated. Defendant Garg did not do either of these legally and procedurally required steps. It was not until February 6, 2020, almost 140 days later that Dr. Yoon heard from Defendant Garg. On this date, Dr. Yoon found out that not only had Defendant Garg failed to conduct a proper inquiry, but Defendant Garg initiated an illegal investigation in December 2019. All of these illegal acts were supported by Defendants Carolee King, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, and V. Suzanne Klimberg. 62. By taking this illegal action, Defendant Garg failed as required by 42 CFR §93.308(a) to provide notice through an inquiry report that a formal investigation was warranted. The notice, if it had been provided would have included a copy of the inquiry report and a reference to 42 CFR part 93 and the UTMB PPMIR. As no notice was given, Defendant Garg violated 42 CFR §93.308(a). As the SIC members were also aware that no notice was given under 42 CFR §93.308(a), Defendants Carolee King, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, and V. Suzanne Klimberg also violated this section of federal law the UTMB PPMIR.
 - 63. Further, Defendant Garg and the Defendants on the December 2019 investigation committee made no effort to document why they failed to meet the legally required sixty (60) daystime limit for the inquiry as required by federal law. More particularly, under 42 CFR § 93.307(g), Defendant Garg and the Defendants on the December 2019 investigation committee were legally required to include any documentation for the reasons they were not able to complete their work within the legally mandated sixty (60) day period. Instead, they broke the law to the great harm and detriment of Dr. Yoon.
 - 64. While Defendant Garg's actions are clearly egregious and highly illegal as are those of the Defendants of the December 2019 investigation committee, one cannot be amazed at the behavior of Defendant Carolee King. In December 2019 when the investigation committee met,

Defendant King was the General Counsel of UTMB. As the top lawyer at UTMB, one would

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reasonably expect that Defendant King would have been fluent in both the federal laws as set forth in 42 CFR part 93 and the UTMB PPMIR. Instead, Defendant King went along with and validated all of the illegal actions of the December 2019 investigation committee and Defendant Garg, including that Dr. Yoon should be fired for his honest mistake. As previously stated, the laws regarding conducting an inquiry and investigation under 42 CFR part 93 are simple to read and understand. Even a first-year law student could figure them out. So, as the lawyer who was a member of the scientific investigation committee of December 2019, it was incumbent upon Defendant Carolee King to provide legal guidance to Defendant Garg and the Defendants on the December 2019 scientific investigation committee. It was Defendant Carolee King's duty to make sure that the Defendants were following a simple-to-read and understandable federal law. This does not absolve Defendant Garg and the Defendants comprising the December 2019 investigation committee of their illegal and bad acts, but Defendant King had an additional obligation as the lawyer on the December 2019 investigation committee to make sure that federal law was being followed as well as the procedures of the UTMB PPMIR. It was Defendant King's duty to ensure that Dr. Yoon's rights were protected. That Dr. Yoon was not harmed and damaged by the process and procedure set forth under the law in 42 CFR part 93 that was reiterated in simple language in the UTMB PPMIR. Instead, as UTMB's top lawyer, and a member of the scientific investigation committee of December 2019, Defendant Carolee King validated, approved and accepted as her own all of Defendants illegal actions and violations of the PPMIR. 65. Of course, in some ways, this was not surprising. Throughout her career, Defendant Carolee King had a habit of breaking laws she should have been aware of. For instance, and quite

Carolee King had a habit of breaking laws she should have been aware of. For instance, and quite infamously, Defendant Carolee King signed an agreement on behalf of UTMB with the Chinese Communist Party ("CCP") and the Wuhan Virology Laboratory, which is notorious for the COVID 19 outbreak. This agreement, which Defendant King signed gave the CCP and Wuhan Virology Laboratory the explicit right to tell UTMB to destroy documents (called "secret files") and materials paid for with Texas state and federal government money. It does not take a genius to figure out that a government attorney like her should have known the document she signed with the CCP was highly

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- illegal. (CCP/Wuhan UTMB Agreement attached as Exhibit I). Moreover, it was not like the sentences giving the CCP and the Wuhan Virology Laboratory this right was hidden. It was located about an inch above her signature right in front of her face. But like her illegal actions with regard to the illegal investigation into Dr. Yoon, Defendant King here again failed to take those steps one would reasonably expect the General Counsel of UTMB to undertake. No, she recklessly and maliciously took those actions that have caused and continue to cause Dr. Yoon great harm.
- 66. Skipping the inquiry phase and heading straight into the illegal investigation, the scientific investigation committee met in person on December 19, 2019. Upon completion of this meeting, an illegal "investigation report" was prepared that was approved by the December 2019 scientific investigation committee on January 2, 2020. Not surprisingly, Defendant UTMB General Counsel Carolee King illegally approved this illegal "investigation report" dated January 2, 2020. (Investigation Report attached as exhibit WW).
- 67. The conclusion of the Defendants comprising the scientific investigation committee of December 2019 that included Defendant Carolee King was that Dr. Yoon should be fired. The illegal "investigation report" was not sent to Dr. Yoon until over a month later on February 6, 2020. In holding an illegal scientific investigation committee meeting in December 2019 and preparing an illegal investigation report that Defendant Garg, Defendant Carolee King and the remaining Defendants comprising the scientific investigation committee of December 2019 knew would destroy Dr. Yoon's career and reputation, these Defendants showed a callous indifference and no regard to the effect their illegal actions would have on Dr. Yoon. Indeed, it is reasonable to conclude that these Defendants had purposefully targeted Dr. Yoon as part of their illegal activities. What is also clear is that not one of these Defendants, including the General Counsel of UTMB, ever said stop. They never took the time to actually read and know the relevant federal laws and UTMB procedures. Nor did they take the time to ensure that they did not violate the fourteenth amendment of the United States Constitution or Article I, Section 19 of the Texas Constitution. No, better to just plow ahead and destroy a good man. Well, these Defendants got what they wanted as their illegal actions have caused serious and significant harm and damage to Dr. Yoon. Having been told he was to be fired in February

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2020; Dr. Yoon has had to live with that horror ever since as Defendants illegal actions continue to this day.

e. Dr. Yoon and Others Identify Illegal Actions of Defendants

- 68. On March 3, 2020, Dr. Yoon along with Dr. Louise Prakash and Dr. Satya Prakash prepared a response to Defendant Garg's and the scientific investigation committee of December 2019 "investigation report." (Letter attached hereto as Exhibit J). In their response, Dr. Yoon along with Dr. Louise Prakash and Dr. Satya Prakash raised serious concerns with the handling of the inquiry/investigation by Defendant Garg, and the December 2019 scientific investigation committee comprising Defendants Carolee King, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, and V. Suzanne Klimberg.
- 69. In short, Dr. Yoon along with Dr. Louise Prakash and Dr. Satya Prakash clearly set forth that all of these Defendants clearly violated the procedures as set forth in the UTMB PPMIR that they were all charged to uphold and follow. They laid out their issues with Defendant Garg's and the scientific investigation committee of December 2019 Defendants' violation of the UTMB PPMIR. Dr. Yoon and company made it clear on a section-by-section basis how Defendant Garg and the scientific investigation committee of December 2019 comprising Defendants Carolee King, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, and V. Suzanne Klimberg failed to abide by even the simplest requirements under the UTMB PPMIR. For instance, Defendant Garg's failure to allow for any comment on an alleged inquiry report that was legally required to initiate an investigation and that an investigation could not be initiated without first completing an inquiry. Defendant Garg also failed to provide the list of names of the scientific investigation committee of December 2019 for prior approval by Dr. Yoon. Nor did Defendant Garg obtain the approval of Defendant President Raimer before initiating an investigation. In essence, as stated above, on March 3, 2020, Defendant Garg was provided clear notification of her and the scientific investigation committee of December 2019 Defendants' violation of the UTMB PPMIR and as a result, violation of multiple sections of federal law as set forth in 42 CFR part 93.
- 70. To start, under the PPMIR, the inquiry requires that Defendant Garg conduct the inquiry to determine if an investigation should even be initiated. According to Section E of the

PPMIR, Charge to the Committee, it is set forth in plain English that the scientific inquiry committee is to determine if an investigation should occur. (See PPMIR attached as Exhibit B). Instead, Defendant Garg blew right past this requirement. Defendant Garg unilaterally determined to move to an investigation and then establish a scientific investigation committee in December 2019, which was comprised of Defendants Carolee King, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, and V. Suzanne Klimberg. What makes this so much worse is that each of these scientific investigation committee members aided and abetted Defendant Garg by going along with her illegal investigation and playing an active role in it. Indeed, knowing that their actions were illegal did not matter to them. These Defendants all were happy to play along with the illegal actions and demand that Dr. Yoon be fired. Not one Defendant on the scientific investigation committee of December 2019 ever stood up to say stop, as they all were breaking the law and violating UTMB's plain English written procedures. Instead, they all gladly took part in an illegal enterprise to cause Dr. Yoon significant damage and harm.

f. SIC of December 2019 Failed to Review Relevant Information

71. What makes all of this worse, is that it is clear from the request in the illegal "investigation report" that changes be implemented in the lab to ensure that the honest mistake of Dr. Yoon never happen again that neither Defendant Garg, nor any member of the December 2019 scientific investigation committee ever read the letters of Dr. Yoon or Dr. Louise Prakash. The problem with this request is that the letters sent by Dr. Louise Prakash and Dr. Yoon in November 2019 clearly stated that such changes had already been made. Thus, not only did Defendant Garg not give Dr. Yoon a chance to testify on behalf of himself, but to the extent he and Dr. Louise Prakash provided exculpatory evidence, Defendant Garg clearly did not provide it to the Defendants on the scientific inquiry committee. The only other explanation is that the Defendants on the scientific investigation committee of 2019 willfully ignored or failed to take the time to read this exculpatory evidence. As stated, Defendant Garg's and the other Defendants' violations of federal law and the UTMB PPMIR just went on and on and on and on...

72. As stated above, for Defendant Carolee King, failing to know or follow federal law is her modus operandi. As has been previously stated, in violation of Texas state and federal law,

Defendant Carolee King signed an agreement with the Wuhan Virology Lab as the General Counsel of UTMB where Defendant Carolee King agreed to let the Chinese Communist Party, which controls the Wuhan Virology lab tell scientists and administrators at UTMB to destroy United States and Texas State funded government documents and materials. (Wuhan UTMB Agreement attached as Exhibit I). In short, Defendant Carolee King has a pattern of breaking federal and state laws and failing miserably to uphold her ethical duties as a lawyer who is a member of the Texas State Bar. To say that Defendant Carolee King is careless is an understatement. Defendant Carolee King has shown callous indifference and wanton recklessness for her failings and frequently flaunting federal and state law without any concern for the harm her actions cause. It is clear that Defendant Carolee King had no issue causing great harm and damage to Dr. Yoon. As a person this is bad enough, as a lawyer her failures rise to a whole different and much greater level that demand justice.

- 73. Defendant Garg as Scientific Integrity Officer was charged with knowing all of the procedures set forth in the UTMB PPMIR and relevant federal law related to an inquiry and investigation of scientific misconduct. Defendant Garg failed to follow the procedures of UTMB that she as UTMB's Scientific Integrity Officer was bound to follow. The December 2019 Scientific investigation committee Defendants were also charged with following the UTMB PPMIR procedures and federal law. They of course failed also and not one of them raised the issue of the illegal actions to the other SIC Defendants or Defendant Garg that each and every one of them was guilty of violating.
- 74. After sending the March 3, 2020, letter expressing their concerns regarding the illegality of the process to date, the hope of Dr. Yoon and the others was that that Defendant Garg would take a step back and retract the illegal "investigation report" that called for the firing of Dr. Yoon. However, as was always the case, Defendant Garg did the wrong thing, continued to break the law and punish Dr. Yoon for what constituted an honest mistake. With Defendant Garg, the illegal actions could not stop. Instead, Defendant Garg would go on to repeat her illegal acts over and over again starting once more in 2021. As will be discussed more below, Defendant Garg was eventually fired as the Scientific Integrity Officer of UTMB as a result of her illegal actions and utterly gross

incompetence, after they were brought to the attention of the General Counsel for the whole University of Texas system Defendant Sharphorn.

g. One Year Later Dr. Garg Renews Defendants Illegal Actions

- 75. So, a year after receiving the March 3, 2020, email from Dr. Yoon, Dr. Louise Prakash and Dr. Satya Prakash, Defendant Garg sent an email on March 23, 2021. In this email, Defendant Garg asked Dr. Louise Prakash if Dr. Yoon had been fired. (Defendant Garg email attached as Exhibit K). In making this request, it is clear that Defendant Garg had not read or was ignoring all her illegal and malicious failures as they had been set forth to her in the March 3, 2020, email from Dr. Yoon, Dr. Louise Prakash and Dr. Satya Prakash. Instead, Defendant Garg decided it was better to compound her malicious and illegal failures, thus ratifying that her actions were indeed wanton, willful and intentional. It is also clear at this point that Defendant Garg and the December 2019 scientific investigation committee Defendants intended for Dr. Yoon to suffer harm and damage from their illegal and unlawful actions. Sadly, their intentional and illegal actions have caused Dr. Yoon great mental, emotional, health and physical damage.
- 76. In Dr. Louse Prakash's and Dr. Satya Prakash's response dated March 25, 2021 to Defendant Garg's March 23, 2021 email, they pointed out to Defendant Garg how perplexed they were that Defendant Garg so wantonly and willfully ignored all of the concerns they had raised in their March 3, 2020 email regarding Defendants' illegal "investigation report" and the failure to follow UTMB's well laid out and simple procedures. (Drs. Prakash letter attached as Exhibit L).

h. Defendant Garg Breaks the Law Again with Communication to NIH ORI

77. Instead of rectifying her mistake, Defendant Garg decided to dig deeper. Defendant Garg sent a letter on June 3, 2021, saying that oops, I made a mistake but no worries. (Defendant Garg email attached as Exhibit M). Defendant Garg announced, I am going to cross off the word "investigation" and write in the word "inquiry" as the header to what was formerly the 2019 "investigation report." Defendant Garg was also removing the paragraph calling for Dr. Yoon's firing from the 2019 "investigation report" and repurposing that same report now as an "inquiry report." Thus, ta-da, like magic, Defendant Garg claimed everything was fixed. Unfortunately, for Dr. Yoon,

Defendant Garg's actions would only extend and perpetuate the torture that he would be forced to suffer at the hands of the Defendants.

- 78. It is likely Defendant Garg took this action in consultation with Defendant Carolee King, UTMB's General Counsel. So now according to Defendant Garg, all is fixed, the world is back to right. However, and not surprising with Defendant Garg, the illegal acts were piling up once again.
- 79. What is also troubling and actually illegal about Defendant Garg's actions is that according to the UTMB PPMIR and federal law, Defendant Garg was not to send the now called "inquiry report" to the National Institutes of Health ("NIH"), Office of Research Integrity ("ORI") until the investigation was approved by the President of UTMB, Defendant Raimer. Instead, Defendant Garg illegally sent the now called "inquiry report" to the NIH ORI prior to her email dated June 3, 2021. This is important as Defendant President Raimer did not approve of the illegal second investigation until June 16, 2021. (Defendant Raimer letter 6/16/22 attached as Exhibit N). So, once again Defendant Garg stepped in and broke federal law and the UTMB PPMIR all at the expense of Dr. Yoon's rights and to his great detriment and harm. Additionally, it is clear that Dr. Garg took this action with the assistance of Defendant Carolee King, who as General Counsel, never failed to violate a federal law or UTMB procedure.

i. Defendant Garg's Initiation of Second Investigation Violated Federal Law

- 80. First, Defendant Garg failed to allow Dr. Yoon to provide comments and a legally required response on the now no longer investigation, but "inquiry report" as required by the UTMB PPMIR and federal law. More particularly, 42 CFR § 93.307(f) that requires that Dr. Yoon be provided "an opportunity to review and comment on the inquiry report and attach any comments received to the report." Once again, Defendant Garg abridged Dr. Yoon's legal due process rights and showed complete disdain for the harm and damage Dr. Yoon suffered and would suffer going forward. Defendant Garg's actions were evil and those one would expect of a monster who cared little for the harm that she caused to those under her control. Defendant Garg should be punished for her actions.
- 81. Additionally, and not surprisingly, based on Defendants clear malevolence against Dr. Yoon as seen through their actions, the alleged now called "inquiry report" failed as required by federal law and the UTMB PPMIR to (i) provide a summary of the inquiry process used, (ii) provide

- a list of the research records reviewed, and (iii) provide a basis for recommending or not recommending that the allegations warrant an investigation as required by federal law and the UTMB PPMIR. Additionally, by not allowing Dr. Yoon to provide a response to the illegal now called "inquiry report," Defendant Garg violated Dr. Yoon's legal rights, including his right to due process.
- 82. Defendant Garg then sent the alleged now called "inquiry report" with all its legal defects to Defendant President Raimer. Not surprisingly, Defendant President Raimer would then fail miserably in his role in this process as the President of UTMB.
- 83. Defendant President Raimer was also charged with knowing the procedures set forth in the UTMB PPMIR and under federal law 42 CFR part 93. But like everyone else at UTMB who voluntarily participated in the crusade against Dr. Yoon, Defendant President Raimer failed to abide by federal law or the UTMB PPMIR. Defendant Raimer, in his role to ensure that Dr. Yoon's rights were not violated, shirked his duty and recklessly endorsed Defendant Garg's and the other Defendants' illegal actions. It was incumbent upon Defendant Raimer to act like a President. Defendant Raimer was to make sure he fully understood everything that had happened to date and to ensure that Dr. Yoon would not be illegally harmed and damaged. But that was too much to ask. Defendant Raimer failed miserably and failed to act as a competent President of UTMB. He allowed Dr. Yoon to suffer harm and damage and to have his due process rights under the law violated.
- 84. Defendant President Raimer compounded, aided and abetted all of the prior illegal actions by agreeing to an investigation in June 2021 based on an illegal and improper investigation report, which was now conveniently relabeled an "inquiry report." Defendant President Raimer in his position of power should have stopped the illegal proceeding in its tracks. But that would have required him to actually perform his job competently and care about doing his job correctly. In the end, Defendant President Raimer with wanton and willful disregard to the law actively participated and allowed the torture of Dr. Yoon to continue to Dr. Yoon's great harm and considerable damage, which continues to grow day-by-day.
- 85. With Defendant President Raimer's written consent to continue the illegal proceeding against Dr. Yoon easily obtained, Defendant Garg started to make additional requests of Dr. Yoon, Dr. Louise Prakash and Dr. Satya Prakash. Now they were allegedly required to provide five years of

any past grants and publications that included Dr. Yoon. Defendant Garg was continuing her reign of terror against Dr. Yoon and dragging others in as part of Defendants' illegal investigation. Additionally, by this time, the whole process had been going on for almost two (2) years.

j. Dr. Yoon Fights Back Against Defendants' Illegal Actions

- 86. At this point, Dr. Yoon decided enough was enough. He fought back. He engaged legal counsel who challenged Defendant Garg about her illegal actions and reckless dereliction of duty as UTMB's Scientific Integrity Officer. (Letter dated July 26, 2021, attached as Exhibit O). This reckless dereliction of duty and unlawful behavior was of course aided and abetted and could not have occurred without the efforts of Defendant President Raimer, Defendant Carolee King and the scientific investigation committee of December 2019 Defendants Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, and V. Suzanne Klimberg in the illegal enterprise. Each of these Defendants willfully and wantonly broke federal law and UTMB policy and procedure in their unlawful persecution of Dr. Yoon.
- 87. Now after the July 26, 2021, letter was sent by Dr. Yoon's legal counsel, it would have been reasonable to expect that Defendant Garg would understand how she failed to run a proper and legal inquiry not once, but now twice. It would have been reasonable to expect that Defendant Garg would now see the error of her unlawful ways and change course. But this is Defendant Garg. So, out comes the shovel and the hole is dug deeper.

k. Defendant Garg Ignores Her Legal Violations and Digs Deeper

88. On September 2, 2021, Defendant Garg sent a letter to Dr. Yoon's legal counsel. (Defendant Garg Letter 9/2/2021 attached as Exhibit P). In this letter, Defendant Garg does not say, oops, let's restart and do the whole thing legally and procedurally correct. No, in a sanctimonious tone, which exuded extreme arrogance, Defendant Garg says that she had to continue with her illegal actions because the National Institutes of Health ("NIH") Office of Research Integrity ("ORI") is making her do it. What is left unsaid is the NIH ORI is basing anything it is telling Defendant Garg on the information provided by her to the NIH ORI. In essence, the NIH ORI was acting on information based on the illegal, dishonest, and procedurally flawed actions of Defendant Garg, Defendant Raimer, Defendant King and the December 2019 scientific investigation committee

Defendants Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, and V. Suzanne Klimberg. In essence, Defendant Garg was putting the onus on the NIH ORI for continuing with her illegal "investigation," without informing the NIH ORI that all of the work Defendant Garg and the other Defendants to date had done that the NIH ORI relied upon was based on illegal actions that violated federal law and the UTMB PPMIR.

l. Dr. Garg Reported to University of Texas General Counsel's Office

and with wanton disregard for Dr. Yoon, the law or UTMB's PPMIR, barrel ahead no matter how illegal her actions, even after they were pointed out to her in plain and explicit language over and over again. So, Dr. Yoon had his legal counsel reach out to the University of Texas System legal team in the General Counsel's Office in Austin. More Particularly on September 10, 2021, a telephonic voice message was left with Ana Viera Ayala, Assistant General Counsel in the University of Texas General Counsel's Office. The message requested that Ms. Ayala call Dr. Yoon's legal counsel as he wanted to discuss serious issues related to actions taken against Dr. Yoon by senior administrators and others at UTMB. The expectation was of course that Ms. Ayala or someone in the University of Texas System General Counsel's Office would call Dr. Yoon's legal counsel back. While Dr. Yoon's legal counsel did not explicitly state that the conversation would be considered that of a "Whistle Blower," it was expected that Ms. Ayala would understand that was the intent. Instead, Ms. Ayala referred the matter to Carolanda Bremond, an Associate Vice President of Legal Affairs at UTMB in the litigation group.

90. Dr. Yoon's legal counsel and Ms. Bremond spoke on September 10, 2021. During the call, Ms. Bremond was impatient and generally nasty. Ms. Bremond also likely lied about her knowledge of the matter; claiming that she was unaware of what was occurring. At the end of the call, the expectation was that Ms. Bremond would call back to work on a resolution that would not violate federal law or the UTMB PPMIR. However, expectations dashed as Ms. Bremond failed to have the courtesy to follow up with Dr. Yoon's legal counsel, even after he followed up with her about a week after their telephone call. (9/16/2021 email attached as Exhibit Q).

m. The University of Texas General Counsel Contacted

91. With nowhere left to reasonably go within the University of Texas System, Dr. Yoon's legal counsel took the extraordinary step of reaching out to Defendant Daniel Sharphorn, General Counsel for the whole University of Texas System. On September 23, 2021, Dr. Yoon's legal counsel wrote a letter to Defendant Sharphorn setting forth all the illegal actions that had occurred to date.

(Letter to Sharphorn 9/23/2021 attached as Exhibit R). Defendant Sharphorn acknowledged receipt of the letter on the next day. (Email Defendant Sharphorn 9/24/2021 attached as Exhibit S).

n. Dr. Garg is Fired

- 92. On October 1, 2021, Defendant Sharphorn telephoned Dr. Yoon's legal counsel. (Call summarized in Letter 10/4/2021 attached as Exhibit T). During that call, Defendant Sharphorn informed Dr. Yoon's legal counsel that Defendant Garg would no longer be responsible for conducting an investigation.
- 93. Of anyone involved in the illegal enterprise set forth herein who should have known the UTMB PPMIR and the federal law as set forth in 42 CFR part 93, it was Defendant Sharphorn. Defendant Sharphorn allegedly worked with the NIH ORI and allegedly helped train people working within the NIH ORI on laws and procedures. But it did not matter, Defendant Sharphorn failed to ensure that any process undertaken against Dr. Yoon going forward would be legal and follow the UTMB PPMIR. Defendant Sharphorn willingly allowed with wanton and reckless disregard for Dr. Yoon's legal rights, including Dr. Yoon's due process rights under the fourteenth amendment of the United States Constitution and Article I, Section 19 of the Texas Constitution to continue to be illegally violated as Defendant Sharphorn stated that yet another inquiry would be initiated.
- 94. What Dr. Yoon learned later is that Defendant Garg was summarily terminated and fired as Scientific Integrity Officer due to her malfeasance, incompetence and her continued and repeated breaking of federal laws and UTMB's PPMIR in her inquisition against Dr. Yoon. The termination of Defendant Garg also clearly constituted an admission by UTMB that Defendants' actions up to that point had been illegal and in violation of federal law and the UTMB PPMIR.
- 95. Now that Defendant Garg had been summarily kicked to the curb in October 2021 for her illegal actions, Dr. Yoon's legal counsel was informed that a new SIO was being appointed to launch a new inquiry. In essence, the whole illegal process that started two years earlier was going to

be started again from the beginning and Dr. Yoon would now have to be dragged through yet another inquiry for his honest mistake.

o. The Second Scientific Integrity Officer and Another Inquiry

- 96. On October 11, 2021, Ms. Bremond sent Dr. Yoon's legal counsel a letter stating that Defendant Niesel had been appointed as the new Scientific Integrity Officer to replace the fired Defendant Garg. Additionally, Defendant Niesel had initiated an alleged new inquiry. (Letter 10/11/2021 attached as Exhibit U). As part of the alleged new inquiry, the January 2, 2020, investigation report would allegedly be disregarded. In essence, the report that told Dr. Yoon he was to be fired almost two (2) years earlier would now be treated as if it did not exist and Dr. Yoon had never been told he was to be fired. The fact that Dr. Yoon had greatly suffered harm and damage during that time and suffered great emotional, mental and physical harm was to be ignored. All was allegedly going to be good now. The reality of course was very different.
- 97. After suffering from over two (2) years of absolutely unreasonable mistreatment, abuse, disparagement and callous indifference by Defendants, Dr. Yoon would now have to repeat this nightmare. What Dr. Yoon was to learn was that the nightmare would continue as Defendants would continue to abuse him through their illegal actions that would violate UTMB's PPMIR and multiple sections of 42 CFR part 93.
- 98. It is important to note that through Ms. Bremond's letter to Dr. Yoon's legal counsel, Dr. Yoon was now notified that an inquiry had been initiated. That meant that October 11, 2021, was the beginning of the legally mandated sixty (60) day period by which the inquiry would have to be completed under federal law (42 CFR §93.307(g)) and the PPMIR. Not surprisingly, the inquiry did not finish and provide Dr. Yoon a report from the scientific inquiry committee of the summer of 2022 for an additional 316 days. This of course meant that the new inquiry lasted over five (5) times longer than the amount of time allowed under the law and the PPMIR. This delay happened despite Defendant Sharphorn promising Dr. Yoon that this new inquiry effort would be conducted within the boundaries of the law and the UTMB PPMIR. It is clear that Defendant Sharphorn aided and abetted the effort to punish Dr. Yoon by breaking federal law and the UTMB PPMIR and violated Dr. Yoon's due process rights.

- 99. On October 14, 2021, UTMB officially announced that Defendant Niesel was appointed to become the new Scientific Integrity Officer, replacing the ignoble and fired-for-incompetence Defendant Garg. (Announcement attached as Exhibit V).
- 100. Since it was clear that Defendant Garg was the one who led the violation of federal law and the UTMB PPMIR with her serious misconduct, a complaint was filed against Defendant Garg with the NIH ORI detailing all her illegal actions and requesting that the NIH ORI initiate an investigation into Defendant Garg. (Complaint with NIH ORI 10/25/2021 attached as Exhibit W). The complaint was sent to Dr. Alexander Runko, Director, Division of Investigative Oversight. Dr. Runko acknowledged receipt of the complaint on October 29, 2021.
- 101. Not hearing anything for almost a year, Dr. Yoon's legal counsel asked for an update on the status of the investigation into Defendant Garg in September 2022. (Runko email attached as Exhibit X). In response, Dr. Runko merely stated that the complaint was open, but no action had been taken by the NIH ORI. As of the filing of this Complaint, Dr. Yoon is not aware that the NIH ORI has taken any action against Defendant Garg. This is not surprising as Defendant Sharphorn worked with the NIH ORI and was well known to them. So, while Dr. Yoon continues to be punished and tortured, those who are part of the "right" team are allowed to go on their merry way, no matter how evil and illegal their actions.

p. Dr. Yoon Files Complaint Against Dr. Garg that is Ignored by UTMB

102. On November 1, 2021, Dr. Yoon along with Dr. Louise Prakash and Dr. Satya Prakash took the step of filing a formal complaint against Defendant Garg with Defendant President Raimer of UTMB. (Complaint attached as Exhibit Y). Ten days later, this complaint was resent to Defendant President Raimer as Dr. Yoon, Dr. Louise Prakash and Dr. Satya Prakash had not received any acknowledgement from Defendant President Raimer that he had received the complaint. Instead, on November 12, 2021, Defendant General Counsel Sharphorn sent a curt email to Dr. Yoon and the others that UTMB would not take any actions to investigate Defendant Garg's blatant, willful and wanton illegal actions and failure to follow UTMB's PPMIR. (Defendant Sharphorn email attached as Exhibit Z). Instead, all the focus would be on Dr. Yoon for his honest mistake.

103. It had become clear that Defendant Sharphorn, the General Counsel of the whole University of Texas System was going to protect Defendant Garg and the other Defendants. It had become clear that Defendants Sharphorn, the General Counsel of the whole University of Texas System would make every effort to sweep all of their illegal actions under the rug while at the same time pursuing Dr. Yoon for a single, honest mistake. Defendant Garg, Defendant Raimer, Defendant King and the Defendants on the scientific investigation committee of December 2019 were not going to be punished for their illegal actions. Instead, the only one to be tried in a kangaroo court without adequate and effective legal representation in violation of his due process rights under the fourteenth amendment of the United States Constitution and Article I, Section 19 of the Texas Constitution would be Dr. Yoon. Thus, a criminal enterprise was protected, and Defendants would not suffer at all thanks to the malfeasance of Defendant Sharphorn.

104. Dr. Yoon, along with Dr. Louise Prakash and Dr. Satya Prakash were stunned at

Defendant Sharphorn's overt act to protect those at UTMB who actually had violated the law and the procedures set forth in UTMB's PPMIR. In response, they sent a letter to Defendant Sharphorn letting him know that they were stupefied and amazed that he would not hold Defendant Garg to account for her illegal actions and willful and wanton disregard of UTMB's procedures set forth in the PPMIR. (Letter to Sharphorn attached as Exhibit AA). They also told Defendant Sharphorn that based on all the illegal and procedurally flawed actions that had occurred at UTMB over more than two years, it was clear that Dr. Yoon could not receive a fair inquiry if it was to be conducted at UTMB. Of course, they were right, and their concerns summarily dismissed.

105. Not caring about Dr. Yoon or the damage and harm he and the other Defendants had and would continue to cause him, Defendant Sharphorn ignored their reasonable plea and set forth with, yet another illegally conducted and procedurally flawed inquiry into Dr. Yoon's innocent mistake in October 2021. Not surprisingly, as of the date of this complaint, there is no evidence that Defendant Garg has ever been held to account for her illegal actions and violation of the UTMB PPMIR by UTMB, by anyone within the University of Texas System or by the NIH ORI.

q. Inquiry Initiated in October 2021 Finally Begins...Almost

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106. It was not until March 2, 2022, that Defendant Niesel, the second Scientific Integrity Officer handling Dr. Yoon's matter contacted Dr. Yoon about the inquiry that had already been initiated on October 11, 2021. (Defendant Niesel letter 3/2/2022 attached as Exhibit BB). Laughingly, in his letter, Defendant Niesel claimed to "come to this role unbiased and focused on helping you and the committee navigate this process." Instead, like all the Defendants before him, Defendant Niesel, broke the law and violated UTMB's PPMIR in this next attempt at running an inquiry into Dr. Yoon's honest mistake.

At the end of his March 2, 2022, letter, Defendant Niesel stated that "I know this is a stressful time for you, but I will work to expedite the process." Of course, almost five (5) months and 142 days had passed since the inquiry had been initiated. If Defendant Niesel were true to his word, the latest the inquiry would end should have been December 11, 2021. This was possible as Defendant Niesel started as Scientific Integrity Officer on October 14, 2021. If one considered wrongly the March 2, 2022, letter as the start of the inquiry, then it would end on May 1, 2022, which is sixty (60) days from the date of his letter. Not surprisingly, Defendant Niesel's words would ring hollow as his actions showed in the end that he cared as little for Dr. Yoon's wellbeing and the truth as the other Defendants before him. It would also not be until August 23, 2022, that Dr. Yoon would finally receive an inquiry report – 174 days after Dr. Yoon received Defendant Niesel's March 2, 2022, letter and over ten (10) months after the October 11, 2021, initiation of this latest inquiry.

> r. Dr. Yoon Request of Meeting to Ensure What Constitutes Scientific Misconduct is Easily Understandable by Scientific Inquiry Committee of Summer of 2022 is Summarily Rejected by Defendants

108. The next day, March 3, 2022, Dr. Yoon's legal counsel sent a letter to Defendant Niesel asking to have a meeting to ensure that the new inquiry is clear on the standards upon which Dr. Yoon was to be judged. (Letter 3/3/2022 attached as Exhibit CC). As was obvious from the multiple failed and illegal prior inquiries conducted under fired SIO Defendant Garg, the UTMB Defendants did not appear to understand the difference between an honest mistake and scientific misconduct. For instance, under 42 CFR § 03.104(b), the misconduct must be "committed knowingly, intentionally or recklessly." At this point in March 2022, no Defendant or anyone else had provided

any evidence and support that Dr. Yoon's actions met any of those standards. The hope was that in some manner, the request to clarify what constituted scientific misconduct would ensure that those involved in this latest inquiry would understand what was required to find Dr. Yoon guilty of scientific misconduct. Thus, it was wholly reasonable for Dr. Yoon to want to ensure that the standard he would be judged by would be clearly set forth going forward. To ensure that this request would not slow down the process, four dates over the next two (2) weeks were offered for a meeting.

109. Despite the reasonableness of the request, Defendant Niesel and Defendant Sharphorn had no care that the process be clear and transparent. Instead, on March 16, 2022, Defendant Sharphorn summarily rejected the reasonable request. (Sharphorn email attached as Exhibit DD). The latest inquiry would go forward with no enunciation of the standards. The significance of this failure by Defendants Niesel and Sharphorn to clarify what constituted scientific misconduct became clear from the inquiry report eventually provided to Dr. Yoon on August 23, 2022. Reading this report clearly showed that the scientific inquiry committee of the summer of 2022 did not understand the standard by which Dr. Yoon was to be judged for an allegation of scientific misconduct. This failure of course lays wholly on Defendant Sharphorn, Defendant Niesel and Defendant Hebbar and Defendant King who as part of Defendant Sharphorn's legal team at UTMB were cc'd and agreed to this prejudicial decision.

s. Defendant Niesel Finally Starts to Move the Newest Inquiry Forward ... Partly

110. It was not for another month, forty-seven (47) days after Defendant Niesel sent his March 2, 2022, letter that he stated that he was to begin working on the inquiry that had been initiated in October 2021. This new letter was sent on April 18, 2022, by Defendant Niesel through which he requested a deposition to discuss the alleged misconduct. (Niesel letter attached as Exhibit EE). In this letter, Defendant Niesel stated that while Dr. Yoon could have legal counsel present sitting near him, such counsel would not be allowed to participate or defend him during the deposition. In short, Dr. Yoon was to be denied the ability to have legal counsel object or play an active role in the deposition to protect his interests in a proceeding where Dr. Yoon's employment future and reputation were at stake. Instead, Dr. Yoon's legal counsel could only "advise" him outside of the deposition itself. His counsel was not allowed to object to any of the questions or provide Dr. Yoon with a proper

- defense for what constituted a one-sided deposition that would play a substantive role in Dr. Yoon's future career, his employment and his professional legacy. Defendant Niesel was telling Dr. Yoon, who is not a lawyer or knowledgeable about the law that he was to be denied his due process rights in clear violation of the constitution, federal and state law and more particularly, the fourteenth amendment of the United States Constitution and Article I, Section 19 of the Texas Constitution.
- Defendant Niesel did not schedule Dr. Yoon's deposition until April 26, 2022. Defendant Niesel, after taking a month and a half to ask to schedule Dr. Yoon's deposition, then told Dr. Yoon he would only have five (5) days to respond on the date of the deposition. This pattern of taking as much time as Defendants wanted and then limiting Dr. Yoon to a short response time has been a pattern of conduct by Defendants in violation of Dr. Yoon's constitutional and legal rights. In the end, the actual deposition did not occur until May 19, 2022.

t. Defendant Niesel Agrees Dr. Yoon Owned Up to His Mistake

- Dr. Yoon was questioned by Defendant Niesel during the deposition on May 19, 2022. Dr Yoon answered all of Defendant Niesel's questions. As part of his preparation for his deposition, Dr. Yoon had prepared a PowerPoint presentation with the evidence to show that what had occurred was an honest mistake and that he had owned up to this mistake through the publication of the corrigendum. (PowerPoint presentation attached as Exhibit FF). The presentation also set forth the evidence to show that the results provided by Park in his complaint were actually not those used in the original published Figure S2. In fact, the complaint was full of fake and false alleged evidence. But as stated, not one Defendant has raised this issue regarding the falsity of the results in the complaint with Park at any time. As Dr. Yoon clearly showed, the whole now over three (3) year torture of Dr. Yoon by Defendants to date was based on a fraud. Instead, the inquisition against Dr. Yoon was to continue even if it was knowingly based on fake and false results.
- 113. During his deposition on May 19, 2022, Dr. Yoon owned up to his honest mistake. Defendant Niesel agreed with this fact by citing to Dr. Yoon's filing the corrigendum with the new Figure S2 with Genes & Development. Indeed, Defendant Niesel congratulated Dr. Yoon for publishing the corrigendum and stated:

"So when you contacted the journal, you know I've seen the correction and you know good for you for putting it in and correcting that. I think that's something that's important that when a mistake or when something like that happens that it's corrected in the literature. So you've done that." (May 19, 2022 Niesel interview transcript at 00:32:03.560 – 00.32.22.560).

So, at this point, Defendant Niesel was agreeing that Dr. Yoon had owned his mistake. In fact, "mistake" is the word that Defendant Niesel used. Not fabrication, not plagiarism, not falsification – mistake. Defendant Niesel was right. Unfortunately, like every other Defendant, Defendant Niesel failed to do the right thing at this point and instead let Dr. Yoon continue to be crucified to his great harm and with the expected damage to Dr. Yoon's emotional, physical and mental health.

114. At the end of the interview, Dr. Yoon agreed to provide his PowerPoint presentation that he used at his deposition to Defendant Niesel. Dr. Yoon also agreed to provide all the data and gels he had used to create corrigendum Figure S2 and other documents requested by Defendant Niesel. Indeed, this would provide Defendant Niesel with everything that Dr. Yoon had in his possession and control that was relevant to the ongoing inquiry that had not already been provided to Defendant Garg in September 2019. This included all of the relevant notebooks, computer files and anything else that was relevant. There is nothing else relevant to this matter that Defendants have not already received and had an opportunity to review. As would be expected of someone who committed an honest mistake, Dr. Yoon has been completely transparent throughout the whole process.

115. At the end of the May 19 deposition, Dr. Yoon pleaded with Defendant Niesel to not further delay the process that had at that point gone on for almost three (3) years. Dr. Yoon pleaded with Defendant Niesel that if there was to be any follow up with a scientific inquiry committee that it be undertaken as fast as possible. The reason for this plea is simple. After suffering for almost three (3) years, Dr. Yoon's mental, emotional and physical well-being and health had deteriorated greatly from the unreasonable pressure and stress. He was suffering depression, gastrointestinal distress that affected his ability to eat and on multiple occasions, those close to Dr. Yoon were concerned that he might commit suicide based on the toll the stress from Defendants' illegal actions had taken over almost three (3) years. It should come as no surprise that despite Dr. Yoon's reasonable request, nothing sped up or was done within a reasonable period of time.

u. More Unreasonable Delays of the Inquiry

116. Instead, he had to suffer for another almost three (3) more months and well outside the sixty (60) days maximum allowed by law and the UTMB PPMIR before Dr. Yoon finally was able to sit for his deposition with the Defendants who comprised the scientific inquiry committee of the summer of 2022. The result of this delay was a continued deterioration in Dr. Yoon's emotional, physical and mental state. The toll of Defendants' ongoing torture was overwhelming Dr. Yoon and he was suffering great harm and damage for what can only reasonably considered an honest mistake.

117. On June 8, 2022, after not hearing anything from Defendant Niesel for almost three weeks since the May 19 deposition, Dr. Yoon's legal counsel reached out to Defendant Niesel to offer any assistance by Dr. Yoon to begin to finally expedite the inquiry process. (Email 6/8/22 attached as Exhibit GG). Later that day, Defendant Hebbar stated that Defendant Niesel had received the documents from Dr. Yoon. (Email 6/8/22 attached as Exhibit HH). However, no effort would be made to expedite the inquiry process or take into consideration the harm and damage Dr. Yoon was suffering. Defendants were only too happy to allow Dr. Yoon to suffer harm and damage at their hands.

Defendant Niesel would be meeting with the scientific inquiry committee of the summer of 2022 at the end of June – about one and a half months after Defendant Niesel's May 19 deposition with Dr. Yoon. So instead of a quick turnaround as hoped for by Dr. Yoon following his May 19 deposition, Dr. Yoon would have to suffer through more months of pain and torture. Moreover, the sixty (60) days' time limit as set forth by federal law and the UTMB PPMIR had long been obliterated and passed by this point. It was clear that once again, Dr. Yoon's due process rights were to be violated. Dr. Yoon was to be left hanging in the wind and forced to suffer more and more for making an honest mistake.

119. Almost two more weeks passed and finally Defendant Niesel met with the Defendants that comprised the scientific inquiry committee of summer of 2022. Then, on June 22, 2022, Defendant Niesel emailed Dr. Yoon to say that he had met with the Defendants that comprised the scientific inquiry committee of the summer of 2022 and they had several requests. (Defendant Niesel

1	Email 6/22/22 attached as Exhibit II). Among these was for a notebook that the committee already	
2	had. (Dr. Yoon's legal counsel Email 6/22/22 attached as Exhibit JJ). Defendant Niesel also stated	
3	that the Defendants that comprised the scientific inquiry committee wanted to take Dr. Yoon's	
4	deposition, but that it would have to wait for at least another three (3) weeks. This continued delay	
5	and plodding of the new inquiry was in violation of federal law and the UTMB PPMIR as was clearly	
6	pointed out by Dr. Yoon's counsel:	
7	"We were hoping to get this resolved by now. I believe there is a time limit to the inquiry	
8	under the UTMB PPMIR and federal law, which I believe has been exceeded. I believe it	
9	definitely will be exceeded as we wait until the week of July 18 to do the next meeting."	
10	(Exhibit JJ).	
11	120. Defendant Hebbar responded on June 23, 2022, to Dr. Yoon's counsel's email (Dr.	
12	Yoon's Legal Counsel email 6/23/2022 attached as Exhibit KK) with a claim that the sixty (60) days-	
13	time limit did not start in September 2019 or March 2021 or June 2021 or October 2021 or March	
14	2022. No, according to Defendant Hebbar, the sixty (60) days' time limit did not start until the most	
15	current, most recent scientific inquiry committee of the summer of 2022 met on June 22, 2022.	
16	(Hebbar Email 6/23/22 attached as Exhibit LL). Unfortunately, for Defendant Hebbar, delaying the	
17	"initiation" date of the inquiry to benefit Defendants fails. There is nothing in 42 CFR § 93.307(g)	
18	that requires the initiation to start with the meeting of the scientific inquiry committee. Indeed, a plain	
19	reading of the language of this section clearly shows that the inquiry begins upon its initiation, which	
20	was at the latest Defendant Niesel's letter of March 2, 2022. The relevant section reads:	
21	"(g) Time for completion. The institution must complete the inquiry within 60 calendar days	
22	of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes	
23	longer than 60 days to complete, the inquiry record must include documentation of the	
24	reasons for exceeding the 60-day period." (42 CFR § 93.307(g), found in Exhibit A).	
25	Nowhere does this section state that the initiation begins only after the first meeting of the scientific	
26	inquiry committee. No, the initiation is with the initiation of the inquiry, which at this point was either	
27	four (4) months earlier, nine (9) months earlier, over two (2) years earlier or almost three (3) years	
28	earlier. The initiation was not on June 22, 2022. Moreover, by this date, Defendants were well aware	

- of how long this long, tortuous process had been going on. Defendants were also well aware that Dr. Yoon had been told two and a half years earlier that he was to be fired for his honest mistake. However, and not surprisingly, as throughout the over three (3) years that Dr. Yoon had been made to suffer, at no point had even one Defendant shown an ounce of decency or concern for his wellbeing. No, the Defendants continued to ignore Dr. Yoon's suffering and continued and have continued to cause him great emotional, health and physical harm and damage from their illegal actions. It is also noteworthy that Defendant Sharphorn, the General Counsel of the whole University of Texas System, had not done anything to make any part of the process timely and legal. Defendant Sharphorn, like the other Defendants, just allowed the whole illegal enterprise to plow on and run over Dr. Yoon.
- 121. On June 27, 2022, Defendant Niesel asked Dr. Yoon for even more information. (Email attached as Exhibit MM). In response, Dr. Yoon provided a document that detailed his experiments and work for corrigendum Figure S2. (Detail document attached as Exhibit NN). Additionally, in the email sent with Dr. Yoon's document, his counsel requested that the scientific inquiry committee deposition occur as soon as possible, even the following week. (Dr. Yoon's legal counsel email attached as exhibit OO). Dr. Yoon's counsel was well aware of the terrible harm and damage the long, drawn-out process was having on Dr. Yoon.
- 122. Consistent with Defendants pattern of failing to take into consideration the harm and damage that Defendants' long and drawn-out process was having on Dr. Yoon, Dr. Yoon's offer to be deposed soon was summarily rejected. Another two (2) plus weeks passed with no word on setting Dr. Yoon's deposition date with the scientific inquiry committee of the summer of 2022. It turns out that during this time Defendant Niesel had gone on vacation to take a break and enjoy himself. Meanwhile, Dr. Yoon suffered from the now almost three (3) year torture by Defendants.
- 123. Once again extremely frustrated with the slow pace of the process, Dr. Yoon's legal counsel sent another letter, this time to Defendant Hebbar. (Dr. Yoon's counsel's letter attached as Exhibit PP). The letter again raised the timing of the whole inquiry process and that it violated both federal law and the UTMB PPMIR. The letter further reiterated once again that the delays in the process were causing Dr. Yoon great harm and damage. His mental, emotional and physical well-

being were all greatly suffering from the process that had been going on for way too long and the continual extended delays caused by Defendants.

124. Defendant Hebbar responded the same day, on July 14, 2022 that the scientific inquiry committee was working on scheduling the deposition on August 8, 9 or 10, 2022. (Hebbar email attached as Exhibit QQ). Finally, after many weeks, Dr. Yoon's deposition with the scientific inquiry committee was eventually scheduled for August 8, 2022, adding another forty-one (41) days to the inquiry.

v. Dr. Yoon Sits for a Second Deposition By Himself as His Legal Counsel was Barred from Participating

125. Dr. Yoon sat for his deposition with the scientific committee on August 8, 2022. As had become the standard for these depositions, Dr. Yoon was denied effective counsel. He was allowed to have counsel sit near to him, but counsel was to stay quiet and could not speak on his behalf. Counsel could not object or ask for clarification. Instead, it was eight against one, with the Defendants comprising the scientific inquiry committee of the summer of 2022, Defendant Niesel and Defendant Hebbar, UTMB's attorney in violation of his due process rights under the fourteenth amendment of the United States Constitution and Article I, Section 19 of the Texas Constitution. These Defendants were able to gang up on Dr. Yoon, a senior scientist with no experience handling the type of hostile questioning he ended up facing during his deposition.

126. Additionally, when Dr. Yoon's counsel tried to speak on his behalf, for instance to clarify misstatements made by Defendants comprising the scientific inquiry committee of the summer of 2022, Defendant Hebbar stamped down on Dr. Yoon's legal counsel. Defendant Hebbar essentially told Dr. Yoon's legal counsel in violation of Dr. Yoon's due process rights that he was to shut up and how dare he speak to protect Dr. Yoon from the illegal actions of Defendants. More particularly, Defendant Hebbar, following an attempt by Dr. Yoon's legal counsel to protect him from misstatements by the Defendants comprising the scientific inquiry committee of the summer of 2022 told Dr. Yoon's counsel that:

00:36:09.700 – 00:36:19:230 Hebbar, Rohan

"Because again, Doctor Weinstein, I appreciate that you're you know that you're trying to

1	explain what your client is saying, but this is not a meeting for the lawyers to be speaking	
2	on. So.	
3	00:36:18.590 – 00:36:30.780 Peter Weinstein	
4	I appreciate that, but I want to be I I mean, this is very important because the decision of	
5	the Scientific Integrity Committee impacts whether this continues the forward. And let's	
6	be clear on the application is all stop talking.	
7	00:36:25.710 – 00:36:42.540 Hebbar, Rohan	
8	Yeah, but this is it's not. It's not. You're you're a legal representative for Doctor Yoon.	
9	You're not. You're not a scientist. Speaking on his behalf. So please let him speak if you	
10	need to talk to your client offline, you can. You can use your mic and speak to him, but	
11	you're not to address the committee directly."	
12	With these statements, Defendant Hebbar confirmed that Dr. Yoon's legal counsel could not defend	
13	him during his deposition in violation of his due process rights. Instead, Dr. Yoon, who was	
14	frightened, worn down and who had no real understanding of how to legally protect himself during a	
15	hostile deposition, was left to fend for himself. This constituted, as had also happened during his first	
16	deposition on May 19 with Defendant Niesel, a clear violation of Dr. Yoon's due process rights under	
17	the fourteenth amendment of the United States Constitution and Article I, Section 19 of the Texas	
18	Constitution.	
19	127. Defendants' failure to allow Dr. Yoon to have adequate and effective counsel severely	
20	prejudiced him in the matter as Dr. Yoon lacked the skill and knowledge that legal counsel would be	
21	expected to have to provide Dr. Yoon effective counsel. In the end, Defendants sat over Dr. Yoon as	
22	a hangman's jury holding all the power, while Dr. Yoon held none. This appellation would turn out	
23	to be apropos in the end.	
24	w. Another Investigation to be Initiated Without Any Evidence of Scientific	
25	Misconduct	
26	128. On August 23, 2022, Defendant Niesel sent a report prepared by the Defendants who	
27	comprised the scientific inquiry committee of the summer of 2022. Not surprisingly, the hangman's	
28	jury did exactly what was expected. They set out the gallows to hang Dr. Yoon. The Defendants	

1	comprising the scientific inquiry committee called for an investigation of the allegation made by Park
2	with the full knowledge that this would mean that Dr. Yoon would be terminated, and his professional
3	career and reputation ruined. Moreover, Dr. Yoon's torture would continue, which would cause him
4	great emotional, physical and mental harm In fact, upon receiving the report, Dr. Yoon became
5	insolate and highly depressed. Those around him were seriously concerned based on his mental state
6	after three (3) years of continual beat downs by Defendants that Dr. Yoon would commit suicide.
7	129. Not surprisingly, the inquiry report was rife with errors and misstatements about what
8	Dr. Yoon stated during the August 8, 2022, deposition. (Inquiry Report attached as Exhibit RR). The
9	inquiry report also lacked any semblance of evidence to support the request to initiate an investigation.
10	As set out above, for Dr. Yoon to be found guilty of scientific misconduct, under 42 CRR part 93 and
11	the UTMB PPMIR, the Defendants comprising the scientific inquiry committee of the summer of
12	2022 would have to show that Dr. Yoon took his actions with intent or that Dr. Yoon acted recklessly
13	or that it was a deliberate act (knowingly) to commit scientific misconduct. No such finding was
14	made, nor was any evidence presented that would support a claim that Dr. Yoon did anything wrong.
15	Instead, with haughty disregard for a requirement of evidence, the Defendants comprising the
16	scientific inquiry committee of the summer of 2022 provided their judgment based on their own
17	opinions. The problem is that to convict Dr. Yoon and terminate him, there must be some semblance
18	of credible evidence. Here, Defendants failed to provide any evidence of scientific misconduct.
19	130. Further, even by the Defendants comprising the scientific inquiry committee of the
20	summer of 2022's own admission, all that Dr. Yoon is alleged to have done is:
21	"mislabeling, inconsistent record keeping" and an "inability to produce the Western blots for
22	the original Fig. S2." (p. 3 of Inquiry Report attached as Exhibit RR).
23	The Defendants comprising the scientific inquiry committee also claim that:
24	"there is a need for a more thorough investigation as there was a lack of rigor in the approach
25	to assembling this date for the supplementary Figure." (p. 3 of Inquiry Report attached as
26	Exhibit RR).
27	What the Defendants comprising the scientific inquiry committee of the summer of 2022 describe is
28	carelessness. Mislabeling, inconsistent record keeping, lack of rigor in assembling original published

1 Figure S2 is the definition of carelessness. Indeed. defined at carelessness 2 www.dictionary.com/browse/carelessness as: 3 1. "not paying enough attention to what one does;" 4 2. "not exact, accurate or thorough." 5 131. These actions are what Dr. Yoon actually did in putting together the original published 6 Figure S2. He was careless. He made an honest mistake. Even more though, upon learning of his 7 carelessness and honest mistake, he immediately reran the experiments, put together a new Figure S2 8 that was published in a corrigendum where his mistake and carelessness was made public. At no time 9 did Dr. Yoon commit scientific misconduct. Nor after over three (3) years has even one Defendant 10 shown or proven otherwise. 11 132. Additionally, Dr. Yoon admitted to both Defendant Niesel during his May 19, 2022, 12 deposition and to the Defendants comprising the scientific inquiry committee of the summer of 2022 during his deposition on August 8, 2022, that he had made a mistake and had been careless. He has 13 14 never hidden this fact. This does not support a claim of scientific misconduct, which requires intent 15 or that Dr. Yoon acted recklessly or that it was a deliberate act (knowingly). 16 133. Additionally, the Defendants comprising the scientific inquiry committee rely upon 17 claims regarding statements by Dr. Yoon that did not occur during his August 8, 2022, deposition. 18 For instance, the Defendants comprising the scientific inquiry committee claim that Dr. Yoon: 19 "presented slides of his data and offered information for the incorrect data in the original Fig. 20 S2." (p. 3 of Inquiry Report attached as Exhibit RR). 21 "The respondent stated that...incorrect data being utilized was an honest mistake." 22 Dr. Yoon never stated that the data was incorrect. All Dr. Yoon stated during both depositions was 23 that he could not prove that all of the results used in the original published Figure 2 were correct. In 24 fact, the original published Figure S2 may contain all the correct results. In fact, Dr. Yoon pointed 25 out that when you compare the results presented in original published Figure S2 with those in the 26 corrigendum Figure S2, the corresponding results of the two figures look essentially the same.

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134.

Defendants comprising the scientific inquiry committee already have all the evidence. There is

Moreover, the fallacy of this decision is borne out on multiple other fronts. The

nothing left to obtain and review. Defendants already took their deposition of Dr. Yoon and ended it before the allotted time for the deposition was over. If they had more questions, they had time to ask. They chose not to. All that the Defendants comprising the scientific inquiry committee of the summer of 2022 are doing, along with the other Defendants, are continuing their callous, malicious and inhumane torture of Dr. Yoon, causing him great harm and damage.

135. One last point on the shoddy work conducted by the Defendants comprising the scientific inquiry committee of the summer of 2022 and Defendant Niesel, who was the Scientific Integrity Officer at that time (he is no longer SIO) is that they failed to question Park. The Defendants comprising the scientific inquiry committee of the summer of 2022 failed to find out why Park filed the complaint with deliberately false results to impugn the reputation of Dr. Yoon. They never felt it necessary to find out why Park filed the complaint that started the process used by Defendants to crucify Dr. Yoon for now over three (3) years. Defendants have never followed up with Park to find out why he submitted false and fake results to support the allegation of scientific misconduct in his complaint. Defendants have had over three (3) years to find out why Park lied to start a malignant process that has so harmed and damaged Dr. Yoon.

and Defendants Niesel, Sharphorn and Hebbar had spent even a little energy to dig into why the complaint was filed, Defendants would have learned that Park was upset at Dr. Yoon and blamed him for Park's failures. Complainant also lied when he stated that he left UTMB because of Dr. Yoon's alleged fraud. (Complainant letter attached as Exhibit SS). The reality is that Park had already obtained a job at a biotech company and planned to leave UTMB. (Park email attached as Exhibit ZZ). So, instead of leaving and moving on, Park hatched a nefarious plan to burn Dr. Yoon on his way out. He filed his complaint and presented results as evidence of Dr. Yoon's alleged scientific misconduct, many of which turned out to *NOT* correspond with what had been published in the original published Figure S2. Lucky for Park, he had Defendants to fulfill his desire to punish and crucify Dr. Yoon for his honest mistake, which he had owned up to when he filed the corrigendum.

x. Defendant *ad interim* President Mouton Ignores Dr. Yoon's Reply to Inquiry Report

- 138. Knowing that his career and reputation now hung in the balance, Dr. Yoon requested to be given until October 21, 2022, to prepare his response. Dr. Yoon first needed time to take a break to try to relieve the stress and pressure that had been building up for three (3) years. But as Defendants always did when it came time to show Dr. Yoon even a modicum of decency, Dr. Yoon's reasonable request was denied. Instead, Dr. Yoon was provided a short period of time to prepare and provide his response.
- 139. Dr. Yoon provided his response on Monday, October 3, 2022. (Response attached as Exhibit TT). The new Scientific Integrity Officer is Defendant Okorodudu. (Defendant Okorodudu introduction email 9/20/2022 attached as Exhibit UU). Prior to filing his response, Dr. Yoon learned that Defendant Niesel was no longer the Scientific Integrity Officer. However, Dr. Yoon is not aware why Defendant Niesel lasted less than one year in that position.
- 140. Dr. Yoon's response to the inquiry report stated clearly all the defects in the inquiry report. It identified the issues related to Defendants' failure to provide even one piece of evidence to support a claim of scientific misconduct or fraud. Instead, Dr. Yoon's reply showed that the scientific inquiry committee's statements confirmed that Dr. Yoon was careless and had committed an honest mistake. Dr. Yoon's response also pointed out the falsity of the statements made by Defendants against Dr. Yoon. Dr. Yoon's response also set forth the incredible prejudice of Park against Dr. Yoon and that the SIO and the Defendants already had all the documents and testimony that could be obtained. Thus, initiating another investigation was pointless. Finally, Dr. Yoon brought out the horror, torture harm and damage he had faced over three (3) years of unremitting inquiry after i
- 141. Dr. Yoon has been reasonably informed that the inquiry report and Dr. Yoon's response was sent to Defendant *ad interim* President Mouton on Wednesday, October 5, 2022. Dr.

Yoon has also been reasonably informed that Defendant *ad interim* President Mouton provided his decision to Defendant Scientific Integrity Officer Okorodudu on Friday October 7, 2022. Defendant Okorodudu provided Defendant Mouton's decision to Dr. Yoon on Monday October 10, 2022. (Investigation decision attached as Exhibit VV).

142. From Defendant Mouton's written decision, it is clear that Defendant Mouton did not read or at a minimum, carefully read, Dr. Yoon's response to the inquiry report. Defendant Mouton merely rubber stamped the Defendants comprising the scientific inquiry committee of the summer of 2022 decision as his own. Defendant Mouton's recklessness and failure to carry out his duty and consider all the information constitutes a significant breach of Dr. Yoon's rights and one that has caused immense and continued damage and harm to Dr. Yoon. Indeed, Dr. Yoon's mental, emotional and physical health have taken another considerable beating all for something that not one Defendant has provided a single shred of evidence substantiating an allegation of scientific misconduct.

143. It is also clear that Dr. Yoon is being illegally railroaded. Dr. Yoon will be fired as that is what this whole illegal process has been driving at from the start. It does not matter that he made an honest mistake and owned up to it by having the corrigendum published. It does not matter that he has *NOT* committed scientific misconduct. That has never mattered to Defendants. Particularly, once Defendant Garg, Defendant Raimer, Defendant Carolee King and the Defendants of the scientific investigation committee of December 2019 called for Dr. Yoon to be fired. Knowing this, Defendant Niesel, Defendant Hebbar, Defendant Sharphorn, Defendant Mouton, Defendant Okorodudu and the Defendants of the scientific inquiry committee of the summer of 2022 of course will call for his termination because any other result will be an overt admission that Defendant Garg, Defendant Raimer, Defendant Carolee King and the Defendants of the scientific investigation committee of December 2019 broke the law and made a fatal mistake when they called for Dr. Yoon to be fired in January 2020. In fact, this issue was raised to Defendant Sharphorn in October 2020, which he summarily dismissed as he failed to show any concerns for Dr. Yoon's wellbeing and kept digging the hole with the other Defendants.

144. As is clear from the recitation provided herein, at many points over the last over three (3) years, each and every Defendant could have stopped this crusade and crucifixion. Each and every

Defendant could have said Dr. Yoon has suffered enough and more than is reasonable for his carelessness and honest mistake. Each and every Defendant could have admitted that there is not one shred of evidence that Dr. Yoon intended to commit scientific fraud and misconduct. Each and every Defendant understood that the power in the situation was always in Defendants hands with regard to Dr. Yoon and that they held the ultimate ability to be his judge, jury and executioner.

breaking the law and violating his due process rights. Each and every Defendant clearly knew what they were doing and maliciously disregarded and showed callous indifference to the suffering, harm and damage Dr. Yoon was suffering at their hands for over three (3) years. Each and every Defendant ensured that Dr. Yoon was not provided effective and adequate legal counsel to protect his interests and defend him during an illegal process that will ultimately come out where the prior illegal investigation ended, with a demand that Dr. Yoon be fired. That his reputation and career should be destroyed. That his ability to obtain his own money from NIH through grants will be seriously, if not irreparably damaged. That his ability to find a job in science will be ended. Each and every Defendant has played their role as part of UTMB's hangman's jury. Each and every Defendant is in plain English just callous, malicious, evil, cruel and inhumane in a way that must be severely punished.

146. Finally, it is common in complaints to state that the Plaintiff has suffered harm and damage. Here, it is important to understand that the harm and damage have materially and adversely affected every aspect of Dr. Yoon's life. Having to live with the sword of Damocles hanging over his head for over three (3) years that threatened his job, his reputation and his ability to provide for his family, it is not surprising that in many ways he is a shell of the man he was when this all began. Dr. Yoon has had to work hard to not be completely physically, emotionally and mentally destroyed. There have been concerns by those close to Dr. Yoon that this situation would push him to commit suicide as his depression at times has been inconsolable. Dr. Yoon has suffered severe gastrointestinal issues caused by the unrelenting stress he has had to live with day after day. Dr. Yoon has serious issues sleeping and has been pushed to the brink of mental breakdown and exhaustion over and over and over again through Defendants illegal actions. His health has suffered as he has significantly aged more than the over three (3) years Defendants have conducted their illegal actions. Not surprisingly,

Dr. Yoon's marriage has suffered as his wife also has stressed the impact of Defendants' illegal actions will have on Dr. Yoon's career and their livelihood. Ironically, the only place that Dr. Yoon has found solace over the last three (3) plus years has been during his time working in the lab and conducting experiments. The rest of his life has been an unrelenting hellscape.

147. In the end, Dr. Yoon has had to live with this nightmare every day and night for over three years for what constituted an honest mistake that he owned up to at the start through his apology published in the corrigendum. No one should have to suffer through the inhumane treatment that each and every Defendant has put Dr. Yoon through. Each and every Defendant must be severely punished for their illegal actions that clearly violated federal law under 42 CFR part 93, UTMB's policies and procedures set forth in the PPMIR and under the fourteenth amendment of the United States Constitution and Article I, Section 19 of the Texas Constitution.

COUNTI

Violation of 42 U.S.C. § 1983

- 148. Plaintiff Dr. Hung-Joon Yoon restates and incorporates by reference paragraphs 1 through 147 above as if fully re-stated herein.
- 149. Section 42 U.S.C. § 1983 provides that "Every person who, under color of any statute, ordinance, regulation, custom or usage, or any State or Territory of the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress."
- 150. Each of Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer, Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, Gracie Vargas are or were employed by UTMB and are or were public employees working for a state governmental entity within the State of Texas when the actions complained of herein occurred.

1	151. Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer,
2	Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H.
3	Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne
4	Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino,
5	and Gracie Vargas' activities and actions as alleged in at least paragraphs 1-150 above constitute a
6	breach of 42 C.F.R. part 93. More particularly, each and every Defendant has breached at least 42
7	CFR §93.301(b)(2), 42 CFR §93.302(a)(2)(i – ii), 42 CFR §93.304(b, e and f), 42 CFR §93.305(b),
8	42 CFR §93.307(a)(1 – 3), 42 CFR §93.307(d)(1 – 2), and 42 CFR §93.307(e – g).
9	152. Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer,
10	Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H.
11	Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne
12	Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino,
13	Gracie Vargas violated Dr. Yoon's rights with willful and wanton disregard for the damage and harm
14	that Defendants caused Dr. Yoon. Further, Dr Yoon has suffered significant and cognizable damages
15	through Defendants actions and their violation of 42 C.F.R. part 93.
16	153. In addition, Section 1 of the fourteenth amendment to the United States Constitution
17	states:
18	"All persons born or naturalized in the United States, and subject to the jurisdiction
19	thereof, are citizens of the United States and of the State wherein they reside. No State
20	shall make or enforce any law which shall abridge the privileges or immunities of
21	citizens of the United States; nor shall any State deprive any person of life, liberty, or
22	property, without due process of law; nor deny to any person within its jurisdiction the
23	equal protection of the laws."
24	154. As stated in paragraphs 1 – 153, Dr. Yoon was not allowed to have legal counsel
25	participate in the depositions that occurred on May 19, 2022, and August 8, 2022, and Defendants
26	failure to ensure that Dr. Yoon had adequate legal counsel to protect his rights throughout the over
27	three years of illegal inquiries and investigations have resulted in Defendants violating Dr. Yoon's

due process rights. Dr. Yoon's due process rights were also violated when all of the Defendants

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1 illegally failed to follow the procedures for an inquiry and investigation as set forth in 42 CFR part 93. 2 Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer, 3 155. 4 Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H. 5 Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne 6 Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, 7 Gracie Vargas activities and actions as alleged in at least paragraphs 1 – 154 above constitute a breach 8 of the due process clause of the fourteenth amendment of the United States Constitution. 9 Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer, 10 Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H. 11 Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne 12 Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, 13 Gracie Vargas violated Dr. Yoon's rights under fourteenth amendment of the United States 14 Constitution with willful and wanton disregard for the damage and harm that Defendants caused Dr. 15 Yoon. Further, Dr Yoon has suffered significant and cognizable damages through Defendants actions 16 and their violation of fourteenth amendment of the United States Constitution. 17 157. As alleged in at least paragraphs 1 – 156, through their violation of 42 C.F.R. part 93 18 and the Fourteenth Amendment to the United States Constitution, Defendants Nisha J. Garg, Carolee 19 King, Daniel Sharphorn, Benjamin Raimer, Charles P. Mouton, David Niesel, Rohan Hebbar, 20 Anthony Okorodudu, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, 21 Rebecca Wong, B. Monte Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, 22 Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, Gracie Vargas have abridged and violated Dr. 23 Yoon's rights and privileges and are thus, in violation of 42 U.S.C. § 1983 and support the claim 24 brought herein. 25 158. Plaintiff Jung-Hoon Yoon seeks recovery of such amount of damages as to reasonably 26 compensate Dr. Yoon for the harm and damages she has suffered and continues to suffer from the 27 illegal actions of Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer,

Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H.

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Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, Gracie Vargas. **COUNT II** Violation of Texas Constitution 159. Plaintiff Dr. Hung-Joon Yoon restates and incorporates by reference paragraphs 1 through 158 above as if fully re-stated herein. Article I, Section 19 of the Texas State Constitution states that: 160. "No citizen of this State shall be deprived of life, liberty, property, privileges or immunities, or in any manner disfranchised, except by the due course of the law of the land." On information and belief, Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, 161. Benjamin Raimer, Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, Gracie Vargas have violated Dr. Yoon's private interest through their illegal actions as alleged in at least paragraphs 1 – 160. Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer, Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, Gracie Vargas through their illegal actions as alleged in at least paragraphs 1 – 160 have deprived Dr. Yoon of his due process rights for which there was no reasonable excuse or purpose. 162. Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer, Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino, Gracie Vargas activities and actions as alleged in at least paragraphs 1 - 161 above constitute a breach of the due process clause of the Article I, Section 19 of the Texas State Constitution.

	163. Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer,		
	Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H.		
	Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne		
	Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makin		
	Gracie Vargas violated Dr. Yoon's rights under Article I, Section 19 of the Texas State Constitution		
	with willful and wanton disregard for the damage and harm that Defendants caused Dr. Yoon. Further		
	Dr Yoon has suffered significant and cognizable damages through Defendants actions and their		
	violation of Article I, Section 19 of the Texas State Constitution.		
	164. As alleged in at least paragraphs 1 – 163, through their violation of Article I, Section		
	19 of the Texas State Constitution, Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn,		
	Benjamin Raimer, Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio		
	Taglialatela, David H. Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte		
	Pettitt, V. Suzanne Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming		
	Tzeng, Shinji Makino, Gracie Vargas have abridged and violated Dr. Yoon's rights and privileges		
	and are thus, in violation of the Texas State Constitution and support the claim brought herein.		
	165. Plaintiff Jung-Hoon Yoon seeks recovery of such amount of damages as to reasonably		
	compensate Dr. Yoon for the harm and damages she has suffered and continues to suffer from the		
	illegal actions of Defendants Nisha J. Garg, Carolee King, Daniel Sharphorn, Benjamin Raimer,		
Charles P. Mouton, David Niesel, Rohan Hebbar, Anthony Okorodudu, Giulio Taglialatela, David H.			
Walker, Lorraine Evangelista, Blake Rasmussen, Rebecca Wong, B. Monte Pettitt, V. Suzanne			
	Klimberg, William Calhoun, Mahmoud Ahmed, Michael Kinsky, Huey-Ming Tzeng, Shinji Makino,		
	Gracie Vargas.		
	PRAYER FOR RELIEF		
	WHEREFORE, Plaintiff asks this Court to enter judgment against Defendants and all persons		
in active concert or participation with them, granting the following relief:			
	A. An award of damages adequate to compensate Plaintiff for the harm and damage he		
	has suffered;		
	B. Increased damages as permitted under 35 U.S.C. § 284;		

C. 1 Reasonable attorneys' fees and costs of court; and Such other relief to which Plaintiff is entitled in law or equity. 2 D. **JURY DEMAND** 3 Plaintiff demands a trial by jury on all issues presented in this Complaint. 4 5 6 7 Dated: November 23, 2022 /s/ Peter D. Weinstein_ Peter D. Weinstein, Ph.D., J.D. By: Texas State Bar No. 24126484 peter.weinstein@entralta.com Entralta P.L.L.C. 4500 Williams Dr. Ste 212, PMB 511 Georgetown, TX 78633 and Graigory B. Fancher Texas State Bar No. 24052016 gfancher@bwwlaw.com Bourland, Wall & Wenzel, P.C. 301 Commerce Ste 2500 Fort Worth, TX 76102 817-877-1088 8 9

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Title 42 - Public Health

Chapter I - Public Health Service, Department of Health and Human Services Subchapter H - Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities

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PART 93 - PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Authority: 42 U.S.C. 216, 241, and 289b.

Source: 70 FR 28384, May 17, 2005, unless otherwise noted.

§ 93.25 Organization of this part.

This part is subdivided into five subparts. Each subpart contains information related to a broad topic or specific audience with special responsibilities as shown in the following table.

In subpart .	You will find provisions related to
Α	General information about this rule.
В	Definitions of terms used in this part.
С	Responsibilities of institutions with PHS support.
D	Responsibilities of the U.S. Department of Health and Human Services and the Office of Research Integrity.
E	Information on how to contest ORI research misconduct findings and HHS administrative actions.

§ 93.50 Special terms.

This part uses terms throughout the text that have special meaning. Those terms are defined in Subpart B of this part.

Subpart A - General

§ 93.100 General policy.

(a) Research misconduct involving PHS support is contrary to the interests of the PHS and the Federal government and to the health and safety of the public, to the integrity of research, and to the conservation of public funds.

(b) The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive Public Health Service (PHS) support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training share responsibility for the integrity of the research process. HHS has ultimate oversight authority for PHS supported research, and for taking other actions as appropriate or necessary, including the right to assess allegations and perform inquiries or investigations at any time. Institutions and institutional members have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and primary responsibility for responding to and reporting allegations of research misconduct, as provided in this part.

§ 93.101 Purpose.

The purpose of this part is to -

- (a) Establish the responsibilities of HHS, PHS, the Office of Research Integrity (ORI), and institutions in responding to research misconduct issues;
- (b) Define what constitutes misconduct in PHS supported research;
- (c) Define the general types of administrative actions HHS and the PHS may take in response to research misconduct; and
- (d) Require institutions to develop and implement policies and procedures for -
 - (1) Reporting and responding to allegations of research misconduct covered by this part;
 - (2) Providing HHS with the assurances necessary to permit the institutions to participate in PHS supported research.
- (e) Protect the health and safety of the public, promote the integrity of PHS supported research and the research process, and conserve public funds.

§ 93.102 Applicability.

- (a) Each institution that applies for or receives PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with this part.
- (b)
 - (1) This part applies to allegations of research misconduct and research misconduct involving:
 - (i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;
 - (ii) PHS supported biomedical or behavioral extramural or intramural research;
 - (iii) PHS supported biomedical or behavioral extramural or intramural research training programs;
 - (iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and
 - (v) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

- (2) This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.
- (c) This part does not supersede or establish an alternative to any existing regulations or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions against Federal employees, or actions taken under the HHS debarment and suspension regulations at 45 CFR part 76 and 48 CFR subparts 9.4 and 309.4.
- (d) This part does not prohibit or otherwise limit how institutions handle allegations of misconduct that do not fall within this part's definition of research misconduct or that do not involve PHS support.

§ 93.103 Research misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- (a) Fabrication is making up data or results and recording or reporting them.
- (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- (d) Research misconduct does not include honest error or differences of opinion.

§ 93.104 Requirements for findings of research misconduct.

A finding of research misconduct made under this part requires that -

- (a) There be a significant departure from accepted practices of the relevant research community; and
- (b) The misconduct be committed intentionally, knowingly, or recklessly; and
- (c) The allegation be proven by a preponderance of the evidence.

§ 93.105 Time limitations.

- (a) Six-year limitation. This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct.
- (b) Exceptions to the six-year limitation. Paragraph (a) of this section does not apply in the following instances:
 - (1) Subsequent use exception. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.
 - (2) Health or safety of the public exception. If ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.
 - (3) "Grandfather" exception. If HHS or an institution received the allegation of research misconduct before the effective date of this part.

§ 93.106 Evidentiary standards.

The following evidentiary standards apply to findings made under this part.

- (a) **Standard of proof.** An institutional or HHS finding of research misconduct must be proved by a preponderance of the evidence.
- (b) Burden of proof.
 - (1) The institution or HHS has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.
 - (2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.
 - (3) The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

§ 93.107 Rule of interpretation.

Any interpretation of this part must further the policy and purpose of the HHS and the Federal government to protect the health and safety of the public, to promote the integrity of research, and to conserve public funds.

§ 93.108 Confidentiality.

- (a) Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however, that:
 - (1) The institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under § 93.403.
 - (2) Under § 93.517(g), HHS administrative hearings must be open to the public.
- (b) Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

§ 93.109 Coordination with other agencies.

- (a) When more than one agency of the Federal government has jurisdiction of the subject misconduct allegation, HHS will cooperate in designating a lead agency to coordinate the response of the agencies to the allegation. Where HHS is not the lead agency, it may, in consultation with the lead agency, take appropriate action to protect the health and safety of the public, promote the integrity of the PHS supported research and research process and conserve public funds.
- (b) In cases involving more than one agency, HHS may refer to evidence or reports developed by that agency if HHS determines that the evidence or reports will assist in resolving HHS issues. In appropriate cases, HHS will seek to resolve allegations jointly with the other agency or agencies.

Subpart B - Definitions

§ 93.200 Administrative action.

Administrative action means -

- (a) An HHS action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of PHS supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds; or
- (b) An HHS action in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any HHS debarment or suspension.

§ 93.201 Allegation.

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official.

§ 93.202 Charge letter.

Charge letter means the written notice, as well as any amendments to the notice, that are sent to the respondent stating the findings of research misconduct and any HHS administrative actions. If the charge letter includes a debarment or suspension action, it may be issued jointly by the ORI and the debarring official.

§ 93.203 Complainant.

Complainant means a person who in good faith makes an allegation of research misconduct.

§ 93.204 Contract.

Contract means an acquisition instrument awarded under the HHS Federal Acquisition Regulation (FAR), 48 CFR Chapter 1, excluding any small purchases awarded pursuant to FAR Part 13.

§ 93.205 Debarment or suspension.

Debarment or suspension means the Government wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contracts, and cooperative agreements under the HHS regulations at 45 CFR part 76 (nonprocurement) and 48 CFR subparts 9.4 and 309.4 (procurement).

§ 93.206 Debarring official.

Debarring official means an official authorized to impose debarment or suspension. The HHS debarring official is either -

- (a) The Secretary; or
- (b) An official designated by the Secretary.

§ 93.207 Departmental Appeals Board or DAB.

Departmental Appeals Board or DAB means, depending on the context -

- (a) The organization, within the Office of the Secretary, established to conduct hearings and provide impartial review of disputed decisions made by HHS operating components; or
- (b) An Administrative Law Judge (ALJ) at the DAB.

§ 93.208 Evidence.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

§ 93.209 Funding component.

Funding component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, e.g., agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS.

§ 93.210 Good faith.

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

§ 93.211 Hearing.

Hearing means that part of the research misconduct proceeding from the time a respondent files a request for an administrative hearing to contest ORI findings of research misconduct and HHS administrative actions until the time the ALJ issues a recommended decision.

§ 93.212 Inquiry.

Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of §§ 93.307-93.309.

§ 93.213 Institution.

Institution means any individual or person that applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, small research institutions, and independent researchers.

§ 93.214 Institutional member.

Institutional member or members means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

§ 93.215 Investigation.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

§ 93.216 Notice.

Notice means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee. Several sections of Subpart E of this part have special notice requirements.

§ 93.217 Office of Research Integrity or ORI.

Office of Research Integrity or ORI means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

§ 93.218 Person.

Person means any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized.

§ 93.219 Preponderance of the evidence.

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

§ 93.220 Public Health Service or PHS.

Public Health Service or PHS means the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

§ 93.221 PHS support.

PHS support means PHS funding, or applications or proposals therefor, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

§ 93.222 Research.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

§ 93.223 Research misconduct proceeding.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

§ 93.224 Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.

§ 93.225 Respondent.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

§ 93.226 Retaliation.

Retaliation for the purpose of this part means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to -

- (a) A good faith allegation of research misconduct; or
- (b) Good faith cooperation with a research misconduct proceeding.

§ 93.227 Secretary or HHS.

Secretary or HHS means the Secretary of HHS or any other officer or employee of the HHS to whom the Secretary delegates authority.

Subpart C - Responsibilities of Institutions

COMPLIANCE AND ASSURANCES

§ 93.300 General responsibilities for compliance.

Institutions under this part must -

- (a) Have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part;
- (b) Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses;
- (c) Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;
- (d) Take all reasonable and practical steps to protect the positions and reputations of good faith
 complainants, witnesses and committee members and protect them from retaliation by respondents and
 other institutional members;
- (e) Provide confidentiality to the extent required by § 93.108 to all respondents, complainants, and research subjects identifiable from research records or evidence;
- (f) Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence;
- (g) Cooperate with HHS during any research misconduct proceeding or compliance review;
- (h) Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; and
- (i) Have an active assurance of compliance.

§ 93.301 Institutional assurances.

- (a) General policy. An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary. PHS funding components may authorize funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI.
- (b) *Institutional Assurance*. The responsible institutional official must assure on behalf of the institution that the institution -
 - (1) Has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and
 - (2) Complies with its own policies and procedures and the requirements of this part.

§ 93.302 Institutional compliance with assurances.

(a) Compliance with assurance. ORI considers an institution in compliance with its assurance if the institution

- (1) Establishes policies and procedures according to this part, keeps them in compliance with this part, and upon request, provides them to ORI, other HHS personnel, and members of the public;
- (2) Takes all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including -
 - (i) Informs the institution's research members participating in or otherwise involved with PHS supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for support from any PHS funding component, about its policies and procedures for responding to allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and
 - (ii) Complies with its policies and procedures and each specific provision of this part.
- (b) **Annual report**. An institution must file an annual report with ORI which contains information specified by ORI on the institution's compliance with this part.
- (c) Additional information. Along with its assurance or annual report, an institution must send ORI such other aggregated information as ORI may request on the institution's research misconduct proceedings covered by this part and the institution's compliance with the requirements of this part.

§ 93.303 Assurances for small institutions.

- (a) If an institution is too small to handle research misconduct proceedings, it may file a "Small Organization Statement" with ORI in place of the formal institutional policies and procedures required by §§ 93.301 and 93.304.
- (b) By submitting a Small Organization Statement, the institution agrees to report all allegations of research misconduct to ORI. ORI or another appropriate HHS office will work with the institution to develop and implement a process for handling allegations of research misconduct consistent with this part.
- (c) The Small Organization Statement does not relieve the institution from complying with any other provision of this part.

§ 93.304 Institutional policies and procedures.

Institutions seeking an approved assurance must have written policies and procedures for addressing research misconduct that include the following -

- (a) Consistent with § 93.108, protection of the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence;
- (b) A thorough, competent, objective, and fair response to allegations of research misconduct consistent with and within the time limits of this part, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses;
- (c) Notice to the respondent, consistent with and within the time limits of this part;
- (d) Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins;
- (e) Opportunity for the respondent to provide written comments on the institution's inquiry report;

- (f) Opportunity for the respondent to provide written comments on the draft report of the investigation, and provisions for the institutional investigation committee to consider and address the comments before issuing the final report;
- (g) Protocols for handling the research record and evidence, including the requirements of § 93.305;
- (h) Appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process;
- (i) Notice to ORI under § 93.318 and notice of any facts that may be relevant to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process;
- (j) Institutional actions in response to final findings of research misconduct;
- (k) All reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made;
- (I) All reasonable and practical efforts to protect or restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against these complainants, witnesses, and committee members; and
- (m) Full and continuing cooperation with ORI during its oversight review under <u>Subpart D of this part</u> or any subsequent administrative hearings or appeals under <u>Subpart E of this part</u>. This includes providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

§ 93.305 Responsibility for maintenance and custody of research records and evidence.

An institution, as the responsible legal entity for the PHS supported research, has a continuing obligation under this part to ensure that it maintains adequate records for a research misconduct proceeding. The institution must -

- (a) Either before or when the institution notifies the respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments;
- (b) Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records;
- (c) Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments; and
- (d) Maintain the research records and evidence as required by § 93.317.

§ 93.306 Using a consortium or other person for research misconduct proceedings.

(a) An institution may use the services of a consortium or person that the institution reasonably determines to be qualified by practice and experience to conduct research misconduct proceedings.

- (b) A consortium may be a group of institutions, professional organizations, or mixed groups which will conduct research misconduct proceedings for other institutions.
- (c) A consortium or person acting on behalf of an institution must follow the requirements of this part in conducting research misconduct proceedings.

THE INSTITUTIONAL INQUIRY

§ 93.307 Institutional inquiry.

- (a) Criteria warranting an inquiry. An inquiry is warranted if the allegation -
 - (1) Falls within the definition of research misconduct under this part;
 - (2) Is within § 93.102; and
 - (3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
- (b) Notice to respondent and custody of research records. At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them. To the extent it has not already done so at the allegation stage, the institution must, on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- (c) **Review of evidence**. The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a full review of all the evidence related to the allegation.
- (d) *Criteria warranting an investigation*. An inquiry's purpose is to decide if an allegation warrants an investigation. An investigation is warranted if there is -
 - (1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, as provided in § 93.102; and
 - (2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.
- (e) *Inquiry report*. The institution must prepare a written report that meets the requirements of this section and § 93.309.
- (f) Opportunity to comment. The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.
- (g) *Time for completion*. The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

§ 93.308 Notice of the results of the inquiry.

- (a) **Notice to respondent.** The institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the institution's policies and procedures adopted under its assurance.
- (b) **Notice to complainants.** The institution may notify the complainant who made the allegation whether the inquiry found that an investigation is warranted. The institution may provide relevant portions of the report to the complainant for comment.

§ 93.309 Reporting to ORI on the decision to initiate an investigation.

- (a) Within 30 days of finding that an investigation is warranted, the institution must provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report which includes the following information -
 - (1) The name and position of the respondent;
 - (2) A description of the allegations of research misconduct;
 - (3) The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
 - (4) The basis for recommending that the alleged actions warrant an investigation; and
 - (5) Any comments on the report by the respondent or the complainant.
- (b) The institution must provide the following information to ORI on request -
 - (1) The institutional policies and procedures under which the inquiry was conducted;
 - (2) The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
 - (3) The charges for the investigation to consider.
- (c) **Documentation of decision not to investigate.** Institutions must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation. Consistent with § 93.317, institutions must keep these records in a secure manner for at least 7 years after the termination of the inquiry, and upon request, provide them to ORI or other authorized HHS personnel.
- (d) **Notification of special circumstances.** In accordance with § 93.318, institutions must notify ORI and other PHS agencies, as relevant, of any special circumstances that may exist.

THE INSTITUTIONAL INVESTIGATION

§ 93.310 Institutional investigation.

Institutions conducting research misconduct investigations must:

- (a) *Time*. Begin the investigation within 30 days after determining that an investigation is warranted.
- (b) **Notice to ORI.** Notify the ORI Director of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements of § 93.307 and § 93.309.

- (c) **Notice to the respondent.** Notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins. The institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation.
- (d) Custody of the records. To the extent they have not already done so at the allegation or inquiry stages, take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. Whenever possible, the institution must take custody of the records -
 - (1) Before or at the time the institution notifies the respondent; and
 - (2) Whenever additional items become known or relevant to the investigation.
- (e) **Documentation**. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations.
- (f) **Ensuring a fair investigation**. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation.
- (g) Interviews. Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation.
- (h) *Pursue leads*. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

§ 93.311 Investigation time limits.

- (a) Time limit for completing an investigation. An institution must complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with § 93.312, and sending the final report to ORI under § 93.315.
- (b) **Extension of time limit**. If unable to complete the investigation in 120 days, the institution must ask ORI for an extension in writing.
- (c) Progress reports. If ORI grants an extension, it may direct the institution to file periodic progress reports.

§ 93.312 Opportunity to comment on the investigation report.

- (a) The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within 30 days of the date on which the respondent received the draft investigation report.
- (b) The institution may provide the complainant a copy of the draft investigation report or relevant portions of that report. The comments of the complainant, if any, must be submitted within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.

§ 93.313 Institutional investigation report.

The final institutional investigation report must be in writing and include:

- (a) Allegations. Describe the nature of the allegations of research misconduct.
- (b) **PHS support.** Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
- (c) *Institutional charge.* Describe the specific allegations of research misconduct for consideration in the investigation.
- (d) **Policies and procedures.** If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.
- (e) Research records and evidence. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
- (f) **Statement of findings.** For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so -
 - (1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
 - (2) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
 - (3) Identify the specific PHS support;
 - (4) Identify whether any publications need correction or retraction;
 - (5) Identify the person(s) responsible for the misconduct; and
 - (6) List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.
- (g) *Comments*. Include and consider any comments made by the respondent and complainant on the draft investigation report.
- (h) Maintain and provide records. Maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

- (a) While not required by this part, if the institution's procedures provide for an appeal by the respondent that could result in a reversal or modification of the findings of research misconduct in the investigation report, the institution must complete any such appeal within 120 days of its filing. Appeals from personnel or similar actions that would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit.
- (b) If unable to complete any appeals within 120 days, the institution must ask ORI for an extension in writing and provide an explanation for the request.
- (c) ORI may grant requests for extension for good cause. If ORI grants an extension, it may direct the institution to file periodic progress reports.

§ 93.315 Notice to ORI of institutional findings and actions.

The institution must give ORI the following:

- (a) Investigation Report. Include a copy of the report, all attachments, and any appeals.
- (b) *Final institutional action*. State whether the institution found research misconduct, and if so, who committed the misconduct.
- (c) Findings. State whether the institution accepts the investigation's findings.
- (d) *Institutional administrative actions*. Describe any pending or completed administrative actions against the respondent.

§ 93.316 Completing the research misconduct process.

- (a) ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues. An institution must notify ORI in advance if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, which must be reported to ORI under § 93.315.
- (b) After consulting with the institution on its basis for closing a case under paragraph (a) of this section, ORI may conduct an oversight review of the institution's handling of the case and take appropriate action including:
 - (1) Approving or conditionally approving closure of the case;
 - (2) Directing the institution to complete its process;
 - (3) Referring the matter for further investigation by HHS; or,
 - (4) Taking a compliance action.

OTHER INSTITUTIONAL RESPONSIBILITIES

§ 93.317 Retention and custody of the research misconduct proceeding record.

(a) **Definition of records of research misconduct proceedings**. As used in this section, the term "records of research misconduct proceedings" includes:

- (1) The records that the institution secures for the proceeding pursuant to §§ 93.305, 93.307(b) and 93.310(d), except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
- (2) The documentation of the determination of irrelevant or duplicate records;
- (3) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by § 93.309(d);
- (4) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to § 93.310(g); and
- (5) The complete record of any institutional appeal covered by § 93.314.
- (b) Maintenance of record. Unless custody has been transferred to HHS under paragraph (c) of this section, or ORI has advised the institution in writing that it no longer needs to retain the records, an institution must maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later.
- (c) Provision for HHS custody. On request, institutions must transfer custody of or provide copies to HHS, of any institutional record relevant to a research misconduct allegation covered by this part, including the research records and evidence, to perform forensic or other analyses or as otherwise needed to conduct an HHS inquiry or investigation or for ORI to conduct its review or to present evidence in any proceeding under subparts D and E of this part.

§ 93.318 Notifying ORI of special circumstances.

At any time during a research misconduct proceeding, as defined in § 93.223, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

- (a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- (b) HHS resources or interests are threatened.
- (c) Research activities should be suspended.
- (d) There is reasonable indication of possible violations of civil or criminal law.
- (e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- (f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- (g) The research community or public should be informed.

§ 93.319 Institutional standards.

- (a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research misconduct.
- (b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution's internal standards of conduct.

Subpart D - Responsibilities of the U.S. Department of Health and Human Services

GENERAL INFORMATION

§ 93.400 General statement of ORI authority.

- (a) ORI review. ORI may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter. The ORI response may include, but is not limited to -
 - (1) Conducting allegation assessments;
 - (2) Determining independently if jurisdiction exists under this part in any matter;
 - (3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;
 - (4) Recommending that HHS should perform an inquiry or investigation or issue findings and taking all appropriate actions in response to the inquiry, investigation, or findings;
 - (5) Notifying or requesting assistance and information from PHS funding components or other affected Federal and state offices and agencies or institutions;
 - (6) Reviewing an institution's findings and process;
 - (7) Making a finding of research misconduct; and
 - (8) Proposing administrative actions to HHS.
- (b) Requests for information. ORI may request clarification or additional information, documentation, research records, or evidence from an institution or its members or other persons or sources to carry out ORI's review.
- (c) HHS administrative actions.
 - (1) In response to a research misconduct proceeding, ORI may propose administrative actions against any person to the HHS and, upon HHS approval and final action in accordance with this part, implement the actions.
 - (2) ORI may propose to the HHS debarring official that a person be suspended or debarred from receiving Federal funds and may propose to other appropriate PHS components the implementation of HHS administrative actions within the components' authorities.
- (d) ORI assistance to institutions. At any time, ORI may provide information, technical assistance, and procedural advice to institutional officials as needed regarding an institution's participation in research misconduct proceedings.
- (e) **Review of institutional assurances.** ORI may review institutional assurances and policies and procedures for compliance with this part.
- (f) Institutional compliance. ORI may make findings and impose HHS administrative actions related to an institution's compliance with this part and with its policies and procedures, including an institution's participation in research misconduct proceedings.

§ 93.401 Interaction with other offices and interim actions.

- (a) ORI may notify and consult with other offices at any time if it has reason to believe that a research misconduct proceeding may involve that office. If ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the Department of Justice (DOJ), the HHS Inspector General (OIG), or other appropriate investigative body. ORI may provide expertise and assistance to the DOJ, OIG, PHS offices, other Federal offices, and state or local offices involved in investigating or otherwise pursuing research misconduct allegations or related matters.
- (b) ORI may notify affected PHS offices and funding components at any time to permit them to make appropriate interim responses to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, and to conserve public funds.
- (c) The information provided will not be disclosed as part of the peer review and advisory committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.

RESEARCH MISCONDUCT ISSUES

§ 93.402 ORI allegation assessments.

- (a) When ORI receives an allegation of research misconduct directly or becomes aware of an allegation or apparent instance of research misconduct, it may conduct an initial assessment or refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.
- (b) If ORI conducts an assessment, it considers whether the allegation of research misconduct appears to fall within the definition of research misconduct, appears to involve PHS supported biomedical or behavior research, research training or activities related to that research or research training, as provided in § 93.102, and whether it is sufficiently specific so that potential evidence may be identified and sufficiently substantive to warrant an inquiry. ORI may review all readily accessible, relevant information related to the allegation.
- (c) If ORI decides that an inquiry is warranted, it forwards the matter to the appropriate institution or HHS component.
- (d) If ORI decides that an inquiry is not warranted it will close the case and forward the allegation in accordance with paragraph (e) of this section.
- (e) ORI may forward allegations that do not fall within the jurisdiction of this part to the appropriate HHS component, Federal or State agency, institution, or other appropriate entity.

§ 93.403 ORI review of research misconduct proceedings.

ORI may conduct reviews of research misconduct proceedings. In conducting its review, ORI may -

- (a) Determine whether there is HHS jurisdiction under this part;
- (b) Consider any reports, institutional findings, research records, and evidence;
- (c) Determine if the institution conducted the proceedings in a timely and fair manner in accordance with this part with sufficient thoroughness, objectivity, and competence to support the conclusions;
- (d) Obtain additional information or materials from the institution, the respondent, complainants, or other persons or sources;

- (e) Conduct additional analyses and develop evidence;
- (f) Decide whether research misconduct occurred, and if so who committed it;
- (g) Make appropriate research misconduct findings and propose HHS administrative actions; and
- (h) Take any other actions necessary to complete HHS' review.

§ 93.404 Findings of research misconduct and proposed administrative actions.

After completing its review, ORI either closes the case without a finding of research misconduct or -

- (a) Makes findings of research misconduct and proposes and obtains HHS approval of administrative actions based on the record of the research misconduct proceedings and any other information obtained by ORI during its review; or
- (b) Recommends that HHS seek to settle the case.

§ 93.405 Notifying the respondent of findings of research misconduct and HHS administrative actions.

- (a) When the ORI makes a finding of research misconduct or seeks to impose or enforce HHS administrative actions, other than debarment or suspension, it notifies the respondent in a charge letter. In cases involving a debarment or suspension action, the HHS debarring official issues a notice of proposed debarment or suspension to the respondent as part of the charge letter. The charge letter includes the ORI findings of research misconduct and the basis for them and any HHS administrative actions. The letter also advises the respondent of the opportunity to contest the findings and administrative actions under Subpart E of this part.
- (b) The ORI sends the charge letter by certified mail or a private delivery service to the last known address of the respondent or the last known principal place of business of the respondent's attorney.

§ 93.406 Final HHS actions.

Unless the respondent contests the charge letter within the 30-day period prescribed in § 93.501, the ORI finding of research misconduct is the final HHS action on the research misconduct issues and the HHS administrative actions become final and will be implemented, except that the debarring official's decision is the final HHS action on any debarment or suspension actions.

§ 93.407 HHS administrative actions.

- (a) In response to a research misconduct proceeding, HHS may impose HHS administrative actions that include but are not limited to:
 - (1) Clarification, correction, or retraction of the research record.
 - (2) Letters of reprimand.
 - (3) Imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of PHS grants, contracts, or cooperative agreements.
 - (4) Suspension or termination of a PHS grant, contract, or cooperative agreement.
 - (5) Restriction on specific activities or expenditures under an active PHS grant, contract, or cooperative agreement.

- (6) Special review of all requests for PHS funding.
- (7) Imposition of supervision requirements on a PHS grant, contract, or cooperative agreement.
- (8) Certification of attribution or authenticity in all requests for support and reports to the PHS.
- (9) No participation in any advisory capacity to the PHS.
- (10) Adverse personnel action if the respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.
- (11) Suspension or debarment under 45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4, or both.
- (b) In connection with findings of research misconduct, HHS also may seek to recover PHS funds spent in support of the activities that involved research misconduct.
- (c) Any authorized HHS component may impose, administer, or enforce HHS administrative actions separately or in coordination with other HHS components, including, but not limited to ORI, the Office of Inspector General, the PHS funding component, and the debarring official.

§ 93.408 Mitigating and aggravating factors in HHS administrative actions.

The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, and conserve public funds. HHS considers aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. HHS may consider other factors as appropriate in each case. The existence or nonexistence of any factor is not determinative:

- (a) *Knowing, intentional, or reckless.* Were the respondent's actions knowing or intentional or was the conduct reckless?
- (b) **Pattern**. Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?
- (c) *Impact*. Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?
- (d) Acceptance of responsibility. Has the respondent accepted responsibility for the misconduct by -
 - (1) Admitting the conduct;
 - (2) Cooperating with the research misconduct proceedings;
 - (3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and
 - (4) Taking steps to correct or prevent the recurrence of the research misconduct.
- (e) Failure to accept responsibility. Does the respondent blame others rather than accepting responsibility for the actions?
- (f) **Retaliation**. Did the respondent retaliate against complainants, witnesses, committee members, or other persons?
- (g) Present responsibility. Is the respondent presently responsible to conduct PHS supported research?

(h) Other factors. Other factors appropriate to the circumstances of a particular case.

§ 93.409 Settlement of research misconduct proceedings.

- (a) HHS may settle a research misconduct proceeding at any time it concludes that settlement is in the best interests of the Federal government and the public health or welfare.
- (b) Settlement agreements are publicly available, regardless of whether the ORI made a finding of research misconduct.

§ 93.410 Final HHS action with no settlement or finding of research misconduct.

When the final HHS action does not result in a settlement or finding of research misconduct, ORI may:

- (a) Provide written notice to the respondent, the relevant institution, the complainant, and HHS officials.
- (b) Take any other actions authorized by law.

§ 93.411 Final HHS action with settlement or finding of research misconduct.

When a final HHS action results in a settlement or research misconduct finding, ORI may:

- (a) Provide final notification of any research misconduct findings and HHS administrative actions to the respondent, the relevant institution, the complainant, and HHS officials. The debarring official may provide a separate notice of final HHS action on any debarment or suspension actions.
- (b) Identify publications which require correction or retraction and prepare and send a notice to the relevant journal.
- (c) Publish notice of the research misconduct findings.
- (d) Notify the respondent's current employer.
- (e) Take any other actions authorized by law.

INSTITUTIONAL COMPLIANCE ISSUES

§ 93.412 Making decisions on institutional noncompliance.

- (a) Institutions must foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research.
- (b) ORI may decide that an institution is not compliant with this part if the institution shows a disregard for, or inability or unwillingness to implement and follow the requirements of this part and its assurance. In making this decision, ORI may consider, but is not limited to the following factors -
 - (1) Failure to establish and comply with policies and procedures under this part;
 - (2) Failure to respond appropriately when allegations of research misconduct arise;
 - (3) Failure to report to ORI all investigations and findings of research misconduct under this part;
 - (4) Failure to cooperate with ORI's review of research misconduct proceedings; or
 - (5) Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.

- (a) An institution's failure to comply with its assurance and the requirements of this part may result in enforcement action against the institution.
- (b) ORI may address institutional deficiencies through technical assistance if the deficiencies do not substantially affect compliance with this part.
- (c) If an institution fails to comply with its assurance and the requirements of this part, HHS may take some or all of the following compliance actions:
 - (1) Issue a letter of reprimand.
 - (2) Direct that research misconduct proceedings be handled by HHS.
 - (3) Place the institution on special review status.
 - (4) Place information on the institutional noncompliance on the ORI Web site.
 - (5) Require the institution to take corrective actions.
 - (6) Require the institution to adopt and implement an institutional integrity agreement.
 - (7) Recommend that HHS debar or suspend the entity.
 - (8) Any other action appropriate to the circumstances.
- (d) If the institution's actions constitute a substantial or recurrent failure to comply with this part, ORI may also revoke the institution's assurance under §§ 93.301 or 93.303.
- (e) ORI may make public any findings of institutional noncompliance and HHS compliance actions.

DISCLOSURE OF INFORMATION

§ 93.414 Notice.

- (a) ORI may disclose information to other persons for the purpose of providing or obtaining information about research misconduct as permitted under the Privacy Act, 5 U.S.C. 552a.
- (b) ORI may publish a notice of final agency findings of research misconduct, settlements, and HHS administrative actions and release and withhold information as permitted by the Privacy Act and the Freedom of Information Act, 5 U.S.C. 552.

Subpart E - Opportunity To Contest ORI Findings of Research Misconduct and HHS **Administrative Actions**

GENERAL INFORMATION

§ 93.500 General policy.

(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and HHS administrative actions, including debarment or suspension, arising under 42 U.S.C. 289b in connection with PHS supported biomedical and behavioral research, research training, or activities related to that research or research training.

- (b) A respondent has an opportunity to contest ORI research misconduct findings and HHS administrative actions under this part, including debarment or suspension, by requesting an administrative hearing before an Administrative Law Judge (ALJ) affiliated with the HHS DAB, when -
 - (1) ORI has made a finding of research misconduct against a respondent; and
 - (2) The respondent has been notified of those findings and any proposed HHS administrative actions, including debarment or suspension, in accordance with this part.
- (c) The ALJ's ruling on the merits of the ORI research misconduct findings and the HHS administrative actions is subject to review by the Assistant Secretary for Health in accordance with § 93.523. The decision made under that section is the final HHS action, unless that decision results in a recommendation for debarment or suspension. In that case, the decision under § 93.523 shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c).
- (d) Where a proposed debarment or suspension action is based upon an ORI finding of research misconduct, the procedures in this part provide the notification, opportunity to contest, and fact-finding required under the HHS debarment and suspension regulations at 45 CFR part 76, subparts H and G, respectively, and 48 CFR Subparts 9.4 and 309.4.

§ 93.501 Opportunity to contest findings of research misconduct and administrative actions.

- (a) Opportunity to contest. A respondent may contest ORI findings of research misconduct and HHS administrative actions, including any debarment or suspension action, by requesting a hearing within 30 days of receipt of the charge letter or other written notice provided under § 93.405.
- (b) Form of a request for hearing. The respondent's request for a hearing must be -
 - (1) In writing;
 - (2) Signed by the respondent or by the respondent's attorney; and
 - (3) Sent by certified mail, or other equivalent (i.e., with a verified method of delivery), to the DAB Chair and ORI.
- (c) Contents of a request for hearing. The request for a hearing must -
 - (1) Admit or deny each finding of research misconduct and each factual assertion made in support of the finding;
 - (2) Accept or challenge each proposed HHS administrative action;
 - (3) Provide detailed, substantive reasons for each denial or challenge;
 - (4) Identify any legal issues or defenses that the respondent intends to raise during the proceeding; and
 - (5) Identify any mitigating factors that the respondent intends to prove.
- (d) Extension for good cause to supplement the hearing request.
 - (1) After receiving notification of the appointment of the ALJ, the respondent has 10 days to submit a written request to the ALJ for supplementation of the hearing request to comply fully with the requirements of paragraph (c) of this section. The written request must show good cause in accordance with paragraph (d)(2) of this section and set forth the proposed supplementation of the hearing request. The ALJ may permit the proposed supplementation of the hearing request in whole or in part upon a finding of good cause.

(2) Good cause means circumstances beyond the control of the respondent or respondent's representative and not attributable to neglect or administrative inadequacy.

HEARING PROCESS

§ 93.502 Appointment of the Administrative Law Judge and scientific expert.

- (a) Within 30 days of receiving a request for a hearing, the DAB Chair, in consultation with the Chief Administrative Law Judge, must designate an Administrative Law Judge (ALJ) to determine whether the hearing request should be granted and, if the hearing request is granted, to make recommended findings in the case after a hearing or review of the administrative record in accordance with this part.
- (b) The ALJ may retain one or more persons with appropriate scientific or technical expertise to assist the ALJ in evaluating scientific or technical issues related to the findings of research misconduct.
 - (1) On the ALJ's or a party's motion to appoint an expert, the ALJ must give the parties an opportunity to submit nominations. If such a motion is made by a party, the ALJ must appoint an expert, either:
 - (i) The expert, if any, who is agreed upon by both parties and found to be qualified by the ALJ; or,
 - (ii) If the parties cannot agree upon an expert, the expert chosen by the ALJ.
 - The ALJ may seek advice from the expert(s) at any time during the discovery and hearing phases of the proceeding. The expert(s) shall provide advice to the ALJ in the form of a written report or reports that will be served upon the parties within 10 days of submission to the ALJ. That report must contain a statement of the expert's background and qualifications. Any comment on or response to a report by a party, which may include comments on the expert's qualifications, must be submitted to the ALJ in accordance with § 93.510(c). The written reports and any comment on, or response to them are part of the record. Expert witnesses of the parties may testify on the reports and any comments or responses at the hearing, unless the ALJ determines such testimony to be inadmissible in accordance with § 93.519, or that such testimony would unduly delay the proceeding.
- (c) No ALJ, or person hired or appointed to assist the ALJ, may serve in any proceeding under this subpart if he or she has any real or apparent conflict of interest, bias, or prejudice that might reasonably impair his or her objectivity in the proceeding.
- (d) Any party to the proceeding may request the ALJ or scientific expert to withdraw from the proceeding because of a real or apparent conflict of interest, bias, or prejudice under paragraph (c) of this section. The motion to disqualify must be timely and state with particularity the grounds for disqualification. The ALJ may rule upon the motion or certify it to the Chief ALJ for decision. If the ALJ rules upon the motion, either party may appeal the decision to the Chief ALJ.
- (e) An ALJ must withdraw from any proceeding for any reason found by the ALJ or Chief ALJ to be disqualifying.

§ 93.503 Grounds for granting a hearing request.

(a) The ALJ must grant a respondent's hearing request if the ALJ determines there is a genuine dispute over facts material to the findings of research misconduct or proposed administrative actions, including any debarment or suspension action. The respondent's general denial or assertion of error for each finding of research misconduct, and any basis for the finding, or for the proposed HHS administrative actions in the charge letter, is not sufficient to establish a genuine dispute.

- (b) The hearing request must specifically deny each finding of research misconduct in the charge letter, each basis for the finding and each HHS administrative action in the charge letter, or it is considered an admission by the respondent. If the hearing request does not specifically dispute the HHS administrative actions, including any debarment or suspension actions, they are considered accepted by the respondent.
- (c) If the respondent does not request a hearing within the 30-day time period prescribed in § 93.501(a), the finding(s) and any administrative action(s), other than debarment or suspension actions, become final agency actions at the expiration of the 30-day period. Where there is a proposal for debarment or suspension, after the expiration of the 30-day time period the official record is closed and forwarded to the debarring official for a final decision.
- (d) If the ALJ grants the hearing request, the respondent may waive the opportunity for any in-person proceeding, and the ALJ may review and decide the case on the basis of the administrative record. The ALJ may grant a respondent's request that waiver of the in-person proceeding be conditioned upon the opportunity for respondent to file additional pleadings and documentation. ORI may also supplement the administrative record through pleadings, documents, in-person or telephonic testimony, and oral presentations.

§ 93.504 Grounds for dismissal of a hearing request.

- (a) The ALJ must dismiss a hearing request if the respondent -
 - (1) Does not file the request within 30 days after receiving the charge letter;
 - (2) Does not raise a genuine dispute over facts or law material to the findings of research misconduct and any administrative actions, including debarment and suspension actions, in the hearing request or in any extension to supplement granted by the ALJ under § 93.501(d);
 - (3) Does not raise any issue which may properly be addressed in a hearing;
 - (4) Withdraws or abandons the hearing request; or
- (b) The ALJ may dismiss a hearing request if the respondent fails to provide ORI with notice in the form and manner required by § 93.501.

§ 93.505 Rights of the parties.

- (a) The parties to the hearing are the respondent and ORI. The investigating institution is not a party to the case, unless it is a respondent.
- (b) Except as otherwise limited by this subpart, the parties may -
 - (1) Be accompanied, represented, and advised by an attorney;
 - (2) Participate in any case-related conference held by the ALJ;
 - (3) Conduct discovery of documents and other tangible items;
 - (4) Agree to stipulations of fact or law that must be made part of the record;
 - (5) File motions in writing before the ALJ;
 - (6) Present evidence relevant to the issues at the hearing;
 - (7) Present and cross-examine witnesses;
 - (8) Present oral arguments;

- (9) Submit written post-hearing briefs, proposed findings of fact and conclusions of law, and reply briefs within reasonable time frames agreed upon by the parties or established by the ALJ as provided in § 93.522; and
- (10) Submit materials to the ALJ and other parties under seal, or in redacted form, when necessary, to protect the confidentiality of any information contained in them consistent with this part, the Privacy Act, the Freedom of Information Act, or other Federal law or regulation.

§ 93.506 Authority of the Administrative Law Judge.

- (a) The ALJ assigned to the case must conduct a fair and impartial hearing, avoid unnecessary delay, maintain order, and assure that a complete and accurate record of the proceeding is properly made. The ALJ is bound by all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS policies and may not refuse to follow them or find them invalid, as provided in paragraph (c)(4) of this section. The ALJ has the authorities set forth in this part.
- (b) Subject to review as provided elsewhere in this subpart, the ALJ may -
 - (1) Set and change the date, time, schedule, and place of the hearing upon reasonable notice to the parties;
 - (2) Continue or recess the hearing in whole or in part for a reasonable period of time;
 - (3) Hold conferences with the parties to identify or simplify the issues, or to consider other matters that may aid in the prompt disposition of the proceeding;
 - (4) Administer oaths and affirmations;
 - (5) Require the attendance of witnesses at a hearing;
 - (6) Rule on motions and other procedural matters;
 - (7) Require the production of documents and regulate the scope and timing of documentary discovery as permitted by this part;
 - (8) Require each party before the hearing to provide the other party and the ALJ with copies of any exhibits that the party intends to introduce into evidence;
 - (9) Issue a ruling, after an *in camera* inspection if necessary, to address the disclosure of any evidence or portion of evidence for which confidentiality is requested under this part or other Federal law or regulation, or which a party submitted under seal;
 - (10) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;
 - (11) Examine witnesses and receive evidence presented at the hearing;
 - (12) Admit, exclude, or limit evidence offered by a party;
 - (13) Hear oral arguments on facts or law during or after the hearing;
 - (14) Upon motion of a party, take judicial notice of facts;
 - (15) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;
 - (16) Conduct any conference or oral argument in person, by telephone, or by audio-visual communication;
 - (17) Take action against any party for failing to follow an order or procedure or for disruptive conduct.

- (c) The ALJ does not have the authority to -
 - (1) Enter an order in the nature of a directed verdict;
 - (2) Compel settlement negotiations;
 - (3) Enjoin any act of the Secretary; or
 - (4) Find invalid or refuse to follow Federal statutes or regulations, Secretarial delegations of authority, or HHS policies.

§ 93.507 Ex parte communications.

- (a) No party, attorney, or other party representative may communicate ex parte with the ALJ on any matter at issue in a case, unless both parties have notice and an opportunity to participate in the communication. However, a party, attorney, or other party representative may communicate with DAB staff about administrative or procedural matters.
- (b) If an *ex parte* communication occurs, the ALJ will disclose it to the other party and make it part of the record after the other party has an opportunity to comment.
- (c) The provisions of this section do not apply to communications between an employee or contractor of the DAB and the ALJ.

§ 93.508 Filing, forms, and service.

- (a) Filing.
 - (1) Unless the ALJ provides otherwise, all submissions required or authorized to be filed in the proceeding must be filed with the ALJ.
 - (2) Submissions are considered filed when they are placed in the mail, transmitted to a private delivery service for the purpose of delivering the item to the ALJ, or submitted in another manner authorized by the ALJ.

(b) Forms.

- (1) Unless the ALJ provides otherwise, all submissions filed in the proceeding must include an original and two copies. The ALJ may designate the format for copies of nondocumentary materials such as videotapes, computer disks, or physical evidence. This provision does not apply to the charge letter or other written notice provided under § 93.405.
- (2) Every submission filed in the proceeding must include the title of the case, the docket number, and a designation of the nature of the submission, such as a "Motion to Compel the Production of Documents" or "Respondent's Proposed Exhibits."
- (3) Every submission filed in the proceeding must be signed by and contain the address and telephone number of the party on whose behalf the document or paper was filed, or the attorney of record for the party.
- (c) Service. A party filing a submission with the ALJ must, at the time of filing, serve a copy on the other party. Service may be made either to the last known principal place of business of the party's attorney if the party is represented by an attorney, or, if not, to the party's last known address. Service may be made by -
 - (1) Certified mail;

- (2) First-class postage prepaid U.S. Mail;
- (3) A private delivery service;
- (4) Hand-delivery; or
- (5) Facsimile or other electronic means if permitted by the ALJ.
- (d) **Proof of service.** Each party filing a document or paper with the ALJ must also provide proof of service at the time of the filing. Any of the following items may constitute proof of service:
 - (1) A certified mail receipt returned by the postal service with a signature;
 - (2) An official record of the postal service or private delivery service;
 - (3) A certificate of service stating the method, place, date of service, and person served that is signed by an individual with personal knowledge of these facts; or
 - (4) Other proof authorized by the ALJ.

§ 93.509 Computation of time.

- (a) In computing any period of time under this part for filing and service or for responding to an order issued by the ALJ, the computation begins with the day following the act or event, and includes the last day of the period unless that day is a Saturday, Sunday, or legal holiday observed by the Federal government, in which case it includes the next business day.
- (b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government must be excluded from the computation.
- (c) Where a document has been filed by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to a respondent's request for hearing under § 93.501.
- (d) Except for the respondent's request for a hearing, the ALJ may modify the time for the filing of any document or paper required or authorized under the rules in this part to be filed for good cause shown. When time permits, notice of a party's request for extension of the time and an opportunity to respond must be provided to the other party.

§ 93.510 Filing motions.

- (a) Parties must file all motions and requests for an order or ruling with the ALJ, serve them on the other party, state the nature of the relief requested, provide the legal authority relied upon, and state the facts alleged.
- (b) All motions must be in writing except for those made during a prehearing conference or at the hearing.
- (c) Within 10 days after being served with a motion, or other time as set by the ALJ, a party may file a response to the motion. The moving party may not file a reply to the responsive pleading unless allowed by the ALJ.
- (d) The ALJ may not grant a motion before the time for filing a response has expired, except with the parties' consent or after a hearing on the motion. However, the ALJ may overrule or deny any motion without awaiting a response.
- (e) The ALJ must make a reasonable effort to dispose of all motions promptly, and, whenever possible, dispose of all outstanding motions before the hearing.

§ 93.511 Prehearing conferences.

- (a) The ALJ must schedule an initial prehearing conference with the parties within 30 days of the DAB Chair's assignment of the case.
- (b) The ALJ may use the initial prehearing conference to discuss -
 - (1) Identification and simplification of the issues, specification of disputes of fact and their materiality to the ORI findings of research misconduct and any HHS administrative actions, and amendments to the pleadings, including any need for a more definite statement;
 - (2) Stipulations and admissions of fact including the contents, relevancy, and authenticity of documents;
 - (3) Respondent's waiver of an administrative hearing, if any, and submission of the case on the basis of the administrative record as provided in § 93.503(d);
 - (4) Identification of legal issues and any need for briefing before the hearing;
 - (5) Identification of evidence, pleadings, and other materials, if any, that the parties should exchange before the hearing;
 - (6) Identification of the parties' witnesses, the general nature of their testimony, and the limitation on the number of witnesses and the scope of their testimony;
 - (7) Scheduling dates such as the filing of briefs on legal issues identified in the charge letter or the respondent's request for hearing, the exchange of witness lists, witness statements, proposed exhibits, requests for the production of documents, and objections to proposed witnesses and documents;
 - (8) Scheduling the time, place, and anticipated length of the hearing; and
 - (9) Other matters that may encourage the fair, just, and prompt disposition of the proceedings.
- (c) The ALJ may schedule additional prehearing conferences as appropriate, upon reasonable notice to or request of the parties.
- (d) All prehearing conferences will be audio-taped with copies provided to the parties upon request.
- (e) Whenever possible, the ALJ must memorialize in writing any oral rulings within 10 days after the prehearing conference.
- (f) By 15 days before the scheduled hearing date, the ALJ must hold a final prehearing conference to resolve to the maximum extent possible all outstanding issues about evidence, witnesses, stipulations, motions and all other matters that may encourage the fair, just, and prompt disposition of the proceedings.

§ 93.512 Discovery.

- (a) **Request to provide documents.** A party may only request another party to produce documents or other tangible items for inspection and copying that are relevant and material to the issues identified in the charge letter and in the respondent's request for hearing.
- (b) **Meaning of documents**. For purposes of this subpart, the term documents includes information, reports, answers, records, accounts, papers, tangible items, and other data and documentary evidence. This subpart does not require the creation of any document. However, requested data stored in an electronic data storage system must be produced in a form reasonably accessible to the requesting party.

- (c) Nondisclosable items. This section does not authorize the disclosure of -
 - (1) Interview reports or statements obtained by any party, or on behalf of any party, of persons whom the party will not call as witness in its case-in-chief;
 - (2) Analyses and summaries prepared in conjunction with the inquiry, investigation, ORI oversight review, or litigation of the case; or
 - (3) Any privileged documents, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.
- (d) Responses to a discovery request. Within 30 days of receiving a request for the production of documents, a party must either fully respond to the request, submit a written objection to the discovery request, or seek a protective order from the ALJ. If a party objects to a request for the production of documents, the party must identify each document or item subject to the scope of the request and state the basis of the objection for each document, or any part that the party does not produce.
 - (1) Within 30 days of receiving any objections, the party seeking production may file a motion to compel the production of the requested documents.
 - (2) The ALJ may order a party to produce the requested documents for *in camera* inspection to evaluate the merits of a motion to compel or for a protective order.
 - (3) The ALJ must compel the production of a requested document and deny a motion for a protective order, unless the requested document is -
 - (i) Not relevant or material to the issues identified in the charge letter or the respondent's request for hearing;
 - (ii) Unduly costly or burdensome to produce;
 - (iii) Likely to unduly delay the proceeding or substantially prejudice a party;
 - (iv) Privileged, including but not limited to documents protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation; or
 - (v) Collateral to issues to be decided at the hearing.
 - (4) If any part of a document is protected from disclosure under paragraph (d)(3) of this section, the ALJ must redact the protected portion of a document before giving it to the requesting party.
 - (5) The party seeking discovery has the burden of showing that the ALJ should allow it.
- (e) Refusal to produce items. If a party refuses to provide requested documents when ordered by the ALJ, the ALJ may take corrective action, including but not limited to, ordering the noncompliant party to submit written answers under oath to written interrogatories posed by the other party or taking any of the actions at § 93.515.

§ 93.513 Submission of witness lists, witness statements, and exhibits.

(a) By 60 days before the scheduled hearing date, each party must give the ALJ a list of witnesses to be offered during the hearing and a statement describing the substance of their proposed testimony, copies of any prior written statements or transcribed testimony of proposed witnesses, a written report of each expert witness to be called to testify that meets the requirements of Federal Rule of Civil Procedure 26(a)(2)(B), and copies of proposed hearing exhibits, including copies of any written statements that a

- party intends to offer instead of live direct testimony. If there are no prior written statements or transcribed testimony of a proffered witness, the party must submit a detailed factual affidavit of the proposed testimony.
- (b) A party may supplement its submission under paragraph (a) of this section until 30 days before the scheduled hearing date if the ALJ determines:
 - (1) There are extraordinary circumstances; and
 - (2) There is no substantial prejudice to the objecting party.
- (c) The parties must have an opportunity to object to the admission of evidence submitted under <u>paragraph</u>
 (a) of this section under a schedule set by the ALJ. However, the parties must file all objections before the final prehearing conference.
- (d) If a party tries to introduce evidence after the deadlines in paragraph (a) of this section, the ALJ must exclude the offered evidence from the party's case-in-chief unless the conditions of paragraph (b) of this section are met. If the ALJ admits evidence under paragraph (b) of this section, the objecting party may file a motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the evidence. The ALJ may not unreasonably deny that motion.
- (e) If a party fails to object within the time set by the ALJ and before the final prehearing conference, evidence exchanged under paragraph (a) of this section is considered authentic, relevant and material for the purpose of admissibility at the hearing.

§ 93.514 Amendment to the charge letter.

- (a) The ORI may amend the findings of research misconduct up to 30 days before the scheduled hearing.
- (b) The ALJ may not unreasonably deny a respondent's motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the amended findings.

§ 93.515 Actions for violating an order or for disruptive conduct.

- (a) The ALJ may take action against any party in the proceeding for violating an order or procedure or for other conduct that interferes with the prompt, orderly, or fair conduct of the hearing. Any action imposed upon a party must reasonably relate to the severity and nature of the violation or disruptive conduct.
- (b) The actions may include -
 - (1) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;
 - (2) Striking pleadings, in whole or in part;
 - (3) Staying the proceedings;
 - (4) Entering a decision by default;
 - (5) Refusing to consider any motion or other action not timely filed; or
 - (6) Drawing the inference that spoliated evidence was unfavorable to the party responsible for its spoliation.

§ 93.516 Standard and burden of proof.

(a) Standard of proof. The standard of proof is the preponderance of the evidence.

(b) Burden of proof.

- (1) ORI bears the burden of proving the findings of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where ORI establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.
- (2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether ORI has carried the burden of proof imposed by this part, the ALJ shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.
- (3) ORI bears the burden of proving that the proposed HHS administrative actions are reasonable under the circumstances of the case. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose HHS administrative actions following a research misconduct proceeding.

§ 93.517 The hearing.

- (a) The ALJ will conduct an in-person hearing to decide if the respondent committed research misconduct and if the HHS administrative actions, including any debarment or suspension actions, are appropriate.
- (b) The ALJ provides an independent *de novo* review of the ORI findings of research misconduct and the proposed HHS administrative actions. The ALJ does not review the institution's procedures or misconduct findings or ORI's research misconduct proceedings.
- (c) A hearing under this subpart is not limited to specific findings and evidence set forth in the charge letter or the respondent's request for hearing. Additional evidence and information may be offered by either party during its case-in-chief unless the offered evidence is -
 - (1) Privileged, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.
 - (2) Otherwise inadmissible under §§ 93.515 or 93.519.
 - (3) Not offered within the times or terms of §§ 93.512 and 93.513.
- (d) ORI proceeds first in its presentation of evidence at the hearing.
- (e) After both parties have presented their cases-in-chief, the parties may offer rebuttal evidence even if not exchanged earlier under §§ 93.512 and 93.513.
- (f) Except as provided in § 93.518(c), the parties may appear at the hearing in person or by an attorney of record in the proceeding.
- (g) The hearing must be open to the public, unless the ALJ orders otherwise for good cause shown. However, even if the hearing is closed to the public, the ALJ may not exclude a party or party representative, persons whose presence a party shows to be essential to the presentation of its case, or expert witnesses.

§ 93.518 Witnesses.

- (a) Except as provided in paragraph (b) of this section, witnesses must give testimony at the hearing under oath or affirmation.
- (b) The ALJ may admit written testimony if the witness is available for cross-examination, including prior sworn testimony of witnesses that has been subject to cross-examination. These written statements must be provided to all other parties under § 93.513.
- (c) The parties may conduct direct witness examination and cross-examination in person, by telephone, or by audio-visual communication as permitted by the ALJ. However, a respondent must always appear inperson to present testimony and for cross-examination.
- (d) The ALJ may exercise reasonable control over the mode and order of questioning witnesses and presenting evidence to -
 - (1) Make the witness questioning and presentation relevant to deciding the truth of the matter; and
 - (2) Avoid undue repetition or needless consumption of time.
- (e) The ALJ must permit the parties to conduct cross-examination of witnesses.
- (f) Upon request of a party, the ALJ may exclude a witness from the hearing before the witness' own testimony. However, the ALJ may not exclude -
 - (1) A party or party representative;
 - (2) Persons whose presence is shown by a party to be essential to the presentation of its case; or
 - (3) Expert witnesses.

§ 93.519 Admissibility of evidence.

- (a) The ALJ decides the admissibility of evidence offered at the hearing.
- (b) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence (FRE). However, the ALJ may apply the FRE where appropriate (e.g., to exclude unreliable evidence).
- (c) The ALJ must admit evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. However, the ALJ may exclude relevant and material evidence if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence under FRE 401-403.
- (d) The ALJ must exclude relevant and material evidence if it is privileged, including but not limited to evidence protected by the attorney-client privilege, the attorney-work product doctrine, or Federal law or regulation.
- (e) The ALJ may take judicial notice of matters upon the ALJ's own initiative or upon motion by a party as permitted under FRE 201 (Judicial Notice of Adjudicative Facts).
 - (1) The ALJ may take judicial notice of any other matter of technical, scientific, or commercial fact of established character.
 - (2) The ALJ must give the parties adequate notice of matters subject to judicial notice and adequate opportunity to show that the ALJ erroneously noticed the matters.

- (f) Evidence of crimes, wrongs, or acts other than those at issue in the hearing is admissible only as permitted under FRE 404(b) (Character Evidence not Admissible to Prove Conduct; Exceptions, Other Crimes).
- (g) Methods of proving character are admissible only as permitted under FRE 405 (Methods of Proving Character).
- (h) Evidence related to the character and conduct of witnesses is admissible only as permitted under FRE Rule 608 (Evidence of Character and Conduct of Witness).
- (i) Evidence about offers of compromise or settlement made in this action is inadmissible as provided in FRE 408 (Compromise and Offers to Compromise).
- (j) The ALJ must admit relevant and material hearsay evidence, unless an objecting party shows that the offered hearsay evidence is not reliable.
- (k) The parties may introduce witnesses and evidence on rebuttal.
- (I) All documents and other evidence offered or admitted into the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.
- (m) Whenever the ALJ excludes evidence, the party offering the evidence may make an offer of proof, and the ALJ must include the offer in the transcript or recording of the hearing in full. The offer of proof should consist of a brief oral statement describing the evidence excluded. If the offered evidence consists of an exhibit, the ALJ must mark it for identification and place it in the hearing record. However, the ALJ may rely upon the offered evidence in reaching the decision on the case only if the ALJ admits it.

§ 93.520 The record.

- (a) HHS will record and transcribe the hearing, and if requested, provide a transcript to the parties at HHS' expense.
- (b) The exhibits, transcripts of testimony, any other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ.
- (c) For good cause shown, the ALJ may order appropriate redactions made to the record at any time.
- (d) The DAB may return original research records and other similar items to the parties or awardee institution upon request after final HHS action, unless under judicial review.

§ 93.521 Correction of the transcript.

- (a) At any time, but not later than the time set for the parties to file their post-hearing briefs, any party may file a motion proposing material corrections to the transcript or recording.
- (b) At any time before the filing of the ALJ's decision and after consideration of any corrections proposed by the parties, the ALJ may issue an order making any requested corrections in the transcript or recording.

§ 93.522 Filing post-hearing briefs.

- (a) After the hearing and under a schedule set by the ALJ, the parties may file post-hearing briefs, and the ALJ may allow the parties to file reply briefs.
- (b) The parties may include proposed findings of fact and conclusions of law in their post-hearing briefs.

§ 93.523 The Administrative Law Judge's ruling.

- (a) The ALJ shall issue a ruling in writing setting forth proposed findings of fact and any conclusions of law within 60 days after the last submission by the parties in the case. If unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify the parties, the Assistant Secretary for Health and the debarring official, if debarment or suspension is under review. The ALJ shall serve a copy of the ruling upon the parties and the Assistant Secretary for Health.
- (b) The ruling of the ALJ constitutes a recommended decision to the Assistant Secretary for Health. The Assistant Secretary for Health may review the ALJ's recommended decision and modify or reject it in whole or in part after determining it, or the part modified or rejected, to be arbitrary and capricious or clearly erroneous. The Assistant Secretary for Health shall notify the parties of an intention to review the ALJ's recommended decision within 30 days after service of the recommended decision. If that notification is not provided within the 30-day period, the ALJ's recommended decision shall become final. An ALJ decision that becomes final in that manner or a decision by the Assistant Secretary for Health modifying or rejecting the ALJ's recommended decision in whole or in part is the final HHS action, unless debarment or suspension is an administrative action recommended in the decision.
- (c) If a decision under § 93.523(b) results in a recommendation for debarment or suspension, the Assistant Secretary for Health shall serve a copy of the decision upon the debarring official and the decision shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c). The decision of the debarring official on debarment or suspension is the final HHS decision on those administrative actions.

POLICY AND PROCEDURE MANUAL ON INTEGRITY IN RESEARCH

Scientific Integrity Committee Approved March 10, 2008 Amended July 13, 2021

I. Introduction

A. General Policy

Misconduct or fraud in research means fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest errors or honest differences in interpretations or judgments of data. Research misconduct is contrary to the interests of science, the State and Federal government, and the health and safety of the public, and is a significant violation of policy at the University of Texas Medical Branch (UTMB). The faculty, staff, and students of UTMB have an affirmative duty to ensure the integrity of all science conducted at UTMB or by UTMB personnel and have a primary responsibility for responding to and reporting allegations of research misconduct to the Scientific Integrity Official at UTMB.

All institutional members will report observed, suspected, or apparent research misconduct to the Scientific Integrity Official or to the UTMB Fraud and Abuse Hotline. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the Scientific Integrity Officer to discuss the suspected research misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, the Scientific Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

Anyone determined to have violated this policy may be disciplined, up to and including termination of employment, dismissal from their academic program, or both.

B. Scope

This document applies to allegations of research misconduct involving:

A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with UTMB. This policy applies to all research activities associated with UTMB, regardless of the source of funding. The scope of this policy includes, but is not necessarily limited to, the following:

- (1) biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information,
- (2) applications or proposals for extramural or intramural support for biomedical or behavioral research, research training or activities related to that research or research training, or
- (3) plagiarism of research records produced in the course of research, research training or

activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for extramural or intramural funds resulted in a grant, contract, cooperative agreement, or other form of support.

(4) plagiarism of any scientific paper, medical report, or review.

This statement of policy and procedures applies only to allegations of research misconduct that occurred within six years of the date the institution or HHS received the allegation.¹

This statement of policy and procedures is intended in part to carry out UTMB's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93.

II. Definitions

Good faith as applied to a Complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant's or witness's position could have based on the information known to the Complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a member of the Scientific Integrity Committee means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Misconduct/fraud in research means fabrication, falsification, plagiarism, or other practices that materially deviate from those that are commonly accepted within the academic community for proposing, conducting, or reporting research. It does not include honest errors or honest differences in interpretations or judgments of data.

Office of Research Integrity or ORI means the office to which the Health & Human Services Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

Person means any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized.

PHS support means Public Health Service funding, or applications or proposals therefor, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

¹ This policy is subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research means a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a Respondent in the course of the research misconduct proceeding.

Respondent means the person who is alleged to have committed scientific misconduct.

Retaliation for the purpose of this part means a significant adverse action taken against a Complainant, witness, or committee member by an institution or one of its members in response to-

- (a) A good faith allegation of research misconduct; or
- (b) Good faith cooperation with a research misconduct proceeding.

Scientific Integrity Committee is a 6 faculty member committee consisting of 2 members from the School of Medicine, 2 from the Graduate School of Biomedical Sciences, 1 from the School of Nursing, and 1 from the School of Allied Health Sciences. They are appointed by the President in consultation with the academic deans. The members serve for 3 years with staggered terms. A quorum for the committee to meet is 3 members. The Scientific Integrity Officer is an *ex officio* member of the committee.

III. Rights and Responsibilities

A. Scientific Integrity Officer (SIO)

The President of UTMB will appoint the Scientific Integrity Officer (SIO), who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. A detailed listing of the responsibilities of the SIO is set forth in Appendix A. These responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI and/or other appropriate regulatory entities of special circumstances, in accordance with Section IV.F. of this policy;
- Sequester research data and evidence pertinent to the allegation of research misconduct in

- accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Notify the Respondent and provide opportunities for him/her to review, comment, or respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;
- Inform Respondents, Complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Ensure that the inquiry and investigation committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other UTMB officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith Complainants, witnesses, and committee members and counter potential or actual retaliation against them by Respondents or other institutional members;
- Keep the President and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI and/or other appropriate regulatory entities as required by 42 CFR Part 93 or other regulations;
- Monitor whether administrative actions taken by the institution and ORI are enforced and take
 appropriate action, or ensure that others take appropriate action, to notify other involved
 parties, such as sponsors, law enforcement agencies, professional societies, and licensing
 boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI and/or other appropriate regulatory entities in accordance with Section VIII.F. of this policy.

B. Complainant

The Complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. The Complainant should be interviewed at the inquiry stage. The Complainant must be interviewed during an investigation and be given the transcript or recording of the interview for correction.

C. Respondent

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and/or investigation. The Respondent is entitled to:

- A good faith effort from the SIO to notify the Respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the

report;

- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or reference to 42 CFR Part 93 or other pertinent regulation, and this policy;
- Be notified in writing of the allegations to be investigated within a reasonable time after the
 determination that an investigation is warranted, but before the investigation begins (within 30
 days after UTMB decides to begin an investigation), and be notified in writing of any new
 allegations, not addressed in the inquiry or in the initial notice of investigation, within a
 reasonable time after the determination to pursue those allegations;
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
- Have interviewed during the investigation any witness who has been reasonably identified by
 the Respondent as having information on relevant aspects of the investigation, have the
 recording or transcript provided to the witness for correction, and have the corrected recording
 or transcript included in the record of investigation; and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

The Respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the SIO and/or other UTMB officials, the President may terminate the institution's review of an allegation that has been admitted. If the research misconduct involves research funded by the U.S. Public Health Service, UTMB's acceptance of the admission and any proposed settlement must be approved by ORI.

D. Role of the President

The President will receive the inquiry report and after consulting with the SIO and/or other institutional officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d) or other relevant regulation.

Any finding that an investigation is warranted must be made in writing by the President and, where the research misconduct involves research funded by the U.S. Public Health Service, must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the President and the SIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.

The President will receive the investigation report and, after consulting with the SIO and/or other institutional officials, decide the extent to which UTMB accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The President shall ensure that the final investigation report, the findings of the President, and a description of any pending or completed administrative actions are provided to ORI as required by law.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the SIO or to the UTMB Fraud and Abuse Hotline. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the SIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the SIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the SIO and will be counseled about appropriate procedures for reporting allegations. Contact information for the SIO can be found at the Scientific Integrity Committee's website: http://research.utmb.edu/si/default.shtm.

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the SIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the SIO or other institutional officials.

C. Confidentiality

The SIO shall, as required by law:

- (1) limit disclosure of the identity of Respondents and Complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and
- (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding.

The SIO will provide periodic notice to the appropriate associate dean for student affairs of any allegation involving a student. The SIO will provide periodic notice to the Graduate Medical Education Office of any allegation involving a medical resident.

D. Protecting Complainants, witnesses, and committee members

No member of the UTMB community may retaliate in any way against Complainants, witnesses, or committee members. Anyone with such information should immediately report any alleged or apparent retaliation against Complainants, witnesses or committee members to the SIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to inform other officials

in UTMB administration to counter any potential or actual retaliation. If there is evidence of retaliation, the SIO and appropriate UTMB administration officials will act to protect against such retaliation and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the SIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the research misconduct proceeding, the SIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for by law and UTMB policies and procedures. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice. Lawyers or other personal advisors may be present at interviews and proceedings, but their participation will be strictly limited to advising the Respondent.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the SIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the President or his designee will, in consultation with other officials at UTMB and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The SIO shall, in consultation with the President, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened:
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the SIO will immediately assess the allegation to

determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified whether it is within the jurisdictional criteria of 42 CFR § 93.102(b) or other applicable law, and whether the allegation falls within the definition of research misconduct. An inquiry must be conducted if these criteria are met.

Ordinarily, an allegation of plagiarism or other misconduct by a student in an educational class setting would not be within the jurisdiction of 42 CFR § 93.102(b) and would be handled by the school according to the appropriate academic or disciplinary policy. Acknowledging this, the SIO and the appropriate student affairs dean will confer regarding the allegations of research misconduct for a student and determine whether the student Respondent's activity at issue was supported by PHS or other third-party sponsors. If the alleged misconduct was supported by PHS or other third-party sponsors, the matter will be handled in accordance with this policy. If not, it will be administratively handled by the student affairs deans in accordance with school policy.

In conducting the assessment, the SIO need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The SIO shall, on or before the date on which the Respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

If the SIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the SIO must make a good faith effort to notify the Respondent in writing, if the Respondent is known. If the inquiry subsequently identifies additional Respondents, they must be notified in writing. On or before the date on which the Respondent is notified, or the inquiry begins, whichever is earlier, the SIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

D. Appointment of the Inquiry Committee

The standing UTMB Scientific Integrity Committee shall function as the inquiry committee. The chair of the SIC shall be the chair of the inquiry proceeding. The committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those

involved with the inquiry and should include some individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. If appropriate, the Scientific Integrity Committee or the SIO will consult with scientists with expertise in the fields at issue in the Complaint.

The SIO will notify the Respondent in writing of the committee membership and give the Respondent five (5) business days to object to the SIO in writing regarding any member of the Scientific Integrity Committee based upon a personal, professional, or financial conflict of interest. The SIO will make the final determination of whether a conflict exists.

E. Charge to the Committee

The SIO will prepare a charge for the Scientific Integrity Committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the Respondent, Complainant and key witnesses, to determine whether an investigation is warranted, <u>not</u> to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation would be warranted if the committee determines:
- there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and
- the allegation may have substance, based on the committee's review during the inquiry; and
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

The SIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The SIO will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee will normally receive a report from the SIO regarding his or her interviews and review of the relevant data or materials. The committee may also, at its discretion, interview the Complainant, the Respondent, and key witnesses, review the transcripts or recordings of those interviews conducted by the SIO, or examine relevant research records and materials. After consultation with the SIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d) or other applicable law. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred. Nor does it normally involve determining definitively who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the Respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved to the satisfaction of the committee. In that case, and if

the misconduct (as described in § I.B. above) involves the U.S. Public Health Service, the SIO shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the President on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the SIO determines that circumstances clearly warrant a longer period. If the SIO approves an extension, the inquiry record must include written documentation of the reasons for the extension.

H. Retention of Records from the Assessment and Inquiry

All records will be retained for a period of seven years from the date of the completion of the proceedings. See also § VIII. E.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information:

- 1) the name and position of the Respondent;
- 2) the names and titles of the committee members;
- 3) the names and titles of any experts consulted;
- 4) a description of the allegations of research misconduct;
- 5) the intramural or extramural support for the underlying activity (for example, for PHS supported research the identifying information should include grant numbers, grant applications, contracts and publications listing PHS support);
- 6) a summary of the inquiry process used;
- 7) a list of the research records reviewed;
- 8) the basis for recommending or not recommending that the allegations warrant an investigation; and
- 9) any comments on the draft report by the Respondent or Complainant.

Modifications should be made as appropriate in consultation with the SIO, the inquiry committee, and legal counsel where appropriate.

B. Notification to the Respondent, Opportunity to Comment, and Institutional Decision

1. Decision by President

The SIO will transmit the final inquiry report and any comments to the President. At the same time,

the SIO shall provide notice to the Respondent of the inquiry report. Notice will include a copy of the inquiry report, a copy of 42 CFR Part 93 for research involving the PHS, and a copy of this policy. The Respondent will have 10 calendar days to submit comments to the President regarding the contents of the inquiry report.

The President will determine in writing whether an investigation is warranted. Normally the President will have ten (10) calendar days, from the Respondent's deadline to submit his or her comments to the President, to make his or her determination. If the President needs more time to make his or her determination, he or she will notify the SIO of same and the reason for the extension, which the SIO will place in the inquiry file. The inquiry is completed when the President makes this determination.

2. Notification to ORI for Misconduct Involving the U.S. Public Health Service

Within 30 calendar days of the President's decision that an investigation is warranted, the SIO will provide ORI with the President's written decision and a copy of the inquiry report. The SIO will also notify those institutional officials who need to know of the President's decision. The SIO must provide the following information to ORI upon request:

- 1) the institutional policies and procedures under which the inquiry was conducted;
- 2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
- 3) the charges to be considered in the investigation.

If the misconduct did not involve PHS, the SIO will determine if any other entities must be notified.

3. Documentation of Decision Not to Investigate

If the President decides that an investigation is not warranted, the SIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI or other regulatory entity of the reasons why an investigation was not conducted. For misconduct involving PHS, these documents must be provided to ORI or other authorized U.S. Department of Health and Human Services personnel upon request.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the President that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health

practice. Federal law requires the findings of the investigation be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the SIO must notify the Respondent in writing of the allegations to be investigated. If the misconduct involves the PHS, on or before the date on which the investigation begins, the SIO must also notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report.

The SIO must also give the Respondent written notice of any *new* allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The SIO will, prior to notifying Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including UTMB's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The President, in consultation with the SIO and other institutional officials as appropriate, will appoint an investigation committee of at least 3 members and committee chair as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the Respondent and Complainant, and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, the President may select committee members from outside the institution.

The President will notify the Respondent of the proposed committee membership to give the Respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The Respondent will have five (5) calendar days to object in writing to any of the members identified for the Investigation Committee, based upon personal, professional, or financial conflicts of interest. The President will make the final determination of whether a conflict exists.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The SIO will define the subject matter of the investigation in a written charge to the committee that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the Respondent;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
- Defines research misconduct;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the Respondent committed research misconduct it must find that a preponderance of the evidence establishes that:
 - 1. research misconduct, as defined in this policy, occurred (Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion);
 - 2. the research misconduct is a significant departure from accepted practices of the relevant research community; and
 - 3. the Respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313 or other applicable law.

2. First Meeting

The SIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this statement of policy and procedures and, where appropriate, 42 CFR Part 93. The SIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the SIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- Interview each Respondent, Complainant, and any other available person who has been_reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the Respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the

investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. Time for Completion

The investigation should be completed within 120 calendar days from the date it is initiated. This deadline includes conducting the investigation, preparing the report of findings, providing the draft report for comment, and issuing a final report. For any misconduct proceeding other than one involving the PHS, the SIO has the discretion to extend for good cause the 120 day deadline.

If the misconduct involves the PHS, if the SIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The SIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports. The deadline for completion of the investigation includes sending the final investigative report to ORI.

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the SIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the Respondent (which may include the Respondent's CV);
- Describes and documents the intramural or extramural support (including for PHS, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support);
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must:
 - 1) identify whether the research misconduct was falsification, fabrication, plagiarism, or other practices that materially deviate from those that are commonly accepted within the academic community for proposing, conducting, or reporting research, and whether it was committed intentionally, knowingly, or recklessly;
 - 2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;
 - 3) identify the specific intramural or extramural support (e.g., PHS);
 - 4) identify whether any publications need correction or retraction;
 - 5) identify the person(s) responsible for the misconduct; and
 - 6) list any current support or known applications or proposals for support that the Respondent

has pending.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The SIO must give the Respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The Respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the SIO. The Respondent's comments must be included and considered in the final report.

2. Complainant

The SIO will provide the Complainant a copy of the draft investigation report, or relevant portions of it, for comment. The Complainant's comments must be submitted in writing within 30 days of the date on which he/she received the draft report, and the comments must be included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the Respondent and Complainant, the SIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the SIO may require that the recipient sign a confidentiality agreement.

C. Decision by the President

The SIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the Respondent's and Complainant's comments are included and considered, and transmit the final investigation report to the President, who will determine in writing:

- (1) whether UTMB accepts the investigation report, its findings, and the recommended institutional actions; and
- (2) the appropriate institutional actions in response to the accepted findings of research misconduct.

If the President's determination is significantly different from the findings of the investigation committee, the President will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the President may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the President will normally notify both the Respondent and the Complainant in writing, as well as any pertinent regulatory agencies (*e.g.*, ORI in the case of misconduct involving PHS). After informing ORI, the President will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in

which falsified reports may have been published, collaborators of the Respondent in the work, or other relevant parties should be notified of the outcome of the case. The SIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Notice to ORI of Institutional Findings and Actions

For any case of misconduct involving PHS, unless an extension has been granted, the SIO must, within the 120-day period for completing the investigation, submit the following to ORI:

- (1) a copy of the final investigation report with all attachments;
- (2) a statement of whether the institution accepts the findings of the investigation report;
- (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and
- (4) a description of any pending or completed administrative actions against the Respondent.

E. Maintaining Records for Review by ORI

For any case of research misconduct involving PHS, the SIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The SIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently.

For cases involving PHS, the SIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except:

- (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or
- (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315

X. Institutional Administrative Actions

If the President determines that research misconduct is substantiated by the findings, with the exception of determinations where the respondent is a student, the President will decide on the appropriate actions to be taken, after consultation with the SIO and, where appropriate, department

chair or non-faculty administrator. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project;
- Letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.
- Restriction of ability to do independent research or submit grants
- Supervision by other faculty of all research related activity and publications

All disciplinary actions will be in accordance with UTMB policy and the rules and regulations of the Board of Regents of the University of Texas System.

Once a determination has been made, Respondents who are students in the School of Medicine, School of Nursing, School of Allied Health Sciences, or the Graduate School of Biomedical Sciences will have disciplinary proceedings pursuant to the associated student disciplinary procedures in the corresponding schools.

XI. Appeals

A. Faculty

If the determination is that the faculty member is to be terminated, the faculty member may appeal pursuant to the Rules and Regulations of the Board of Regents of the University of Texas System. See IHOP § 5.3.10. If the determination resulted in decision to non-renew the faculty member, the faculty member may appeal the non-renewal directly with the Chief Academic Officer. For all other appeals of the determination and discipline, the faculty member may appeal by filing a grievance pursuant to IHOP § 5.3.8 (Faculty Grievance Policy).

B. Non-Faculty Employees

An employee can appeal a determination resulting in dismissal pursuant to IHOP § 3.10.2; determinations resulting in lesser discipline can be grieved pursuant to IHOP § 3.10.3.

C. Students

Students in the School of Medicine, School of Nursing, School of Allied Health Sciences, or the Graduate School of Biomedical Sciences can appeal pursuant to the student disciplinary procedures in the corresponding schools. Students can appeal both the President's determination under this policy, and the discipline determined through the student disciplinary process.

XII. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities under federal law to fully investigate the allegations. If the Respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, for all PHS supported research and where federal law requires, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the SIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the Respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by federal law, the SIO must, at the request of the Respondent, and in consultation with the President. undertake all reasonable and practical efforts to restore the Respondent's reputation. Depending on the particular circumstances and the views of the Respondent, the SIO should consider the following options:

- notifying those individuals aware of or involved in the investigation of the final outcome; and
- publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized.

Any institutional actions to restore the Respondent's reputation should first be approved by the President.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the SIO, in consultation with the President and the department chair or non-faculty administrator, as appropriate, must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The SIO will determine, after consulting with the President and the department chair or non-faculty administrator, as appropriate, and with the Complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them.

D. Allegations Not Made in Good Faith

If relevant, the President, in consultation with the SIO, will determine whether the Complainant's

allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the President determines that there was an absence of good faith, he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

XIII. REFERENCES

Public Health Service Policy on Scientific Misconduct 42 CFR Part 93. Employee Appeal Policy IHOP § 3.10.2. Employee Grievance Policy IHOP § 3.10.3. Faculty Termination Policy IHOP § 5.3.8. Faculty Grievance Policy IHOP § 5.3.10. Student Conduct and Discipline Policy IHOP § 7.1.3.





The University of Texas Medical Branch SCHOOL OF MEDICINE

Dr. Louis Prakash and Dr. Satya Prakash Department of Biochemistry and Molecular Biology UTMB Galveston

September 16, 2019

Dear Dr. L Prakash and Dr. S Prakash

I have received allegations of possible research misconduct in the form of falsification of figures in a manuscript. Specific allegation is against the first author of the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019). The complainant who wishes to remain anonymous alleged that there were discrepancies in Supplemental Figure S2:

Panel A - top left: blot for TLS Pol in NC/Polη samples is from another blot for a different protein.

Panel A - middle left: Polφ data is from another blot for a different protein in different cells, Rev1 blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Poli data are from a blot for another protein.

Panel B- Western blot for Poli and tubulin for NC/Polo samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data

This manuscript cites support from US PHS funds, specifically NIH grants ES022948 and GM126087. As this possible falsification occurs in research funded by NIH, we are bound to conduct an inquiry to determine whether there is evidence of potential falsification to warrant and investigation.

As a part of inquiry, we may need to sequester all relevant digital and hard copy research records related to the questioned work so that they can be reviewed by the Scientific Integrity Committee at the UTMB.

Sincerely

Nisha J Garg (PHD MBA) Scientific Integrity Officer

UTMB Galveston

RESEARCH COMMUNICATION

DNA polymerase θ accomplishes translesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satya Prakash

Department of Biochemistry and Molecular Biology, University of Texas Medical Branch at Galveston, Galveston, Texas 77555, USA

Here we show that translesion synthesis (TLS) opposite 1, N^6 -ethenodeoxyadenosine (ϵdA), which disrupts Watson—Crick base pairing, occurs via $Polt/Pol\zeta$ -, Rev1-, and $Pol\theta$ -dependent pathways. The requirement of $Polt/Pol\zeta$ is consistent with the ability of Polt to incorporate nucleotide opposite ϵdA by Hoogsteen base pairing and of $Pol\zeta$ to extend synthesis. Rev1 polymerase and $Pol\theta$ conduct TLS opposite ϵdA via alternative error-prone pathways. Strikingly, in contrast to extremely error-prone TLS opposite ϵdA by purified $Pol\theta$, it performs predominantly error-free TLS in human cells. Reconfiguration of the active site opposite ϵdA would provide $Pol\theta$ the proficiency for error-free TLS in human cells.

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The1,N⁶-ethenodeoxyadenosine (εdA) adduct is formed in DNA through interaction with aldehydes derived from lipid peroxidation and by exposure to chemical carcinogens such as vinyl chloride. Lipid peroxidation is a normal chain reaction process that initiates from the oxidation of polyunsaturated fatty acids in cell membranes and results in the formation of a variety of highly reactive aldehydes, including acrolein, malonaldehyde, and *trans*-4-hydroxy-2-nonenal (HNE). Enals such as HNE undergo further oxidation reactions to form epoxyaldehydes and the reaction of epoxyaldehyde with DNA generates the εdA adduct (Chung et al. 1999; Luczaj and Skrzydlewska 2003).

The &dA adduct is highly inhibitory to synthesis by replicative DNA polymerases (Pols) because the exocyclic ring between the N1 and N6 positions of &dA impairs the Watson–Crick (W–C) edge of adenine (Supplemental Fig. S1). The ability of the Poli active site to push template purines into a *syn* conformation provides a mechanism by which this polymerase can insert nucleotides opposite DNA lesions which disrupt W–C base pairing. Biochemi-

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Corresponding author: loprakas@utmb.edu

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cal studies have shown that while Poli incorporates a T correctly opposite the εdA adduct, it also incorporates a C with an about one fourth efficiency of that of T incorporation (Nair et al. 2006). Crystal structures of PoliεdA·dTTP and Pol-εdA·dCTP ternary complexes show that similar to nonadducted A, the εdA adduct adopts a syn conformation in the Poliactive site and its "Hoogsteen edge" participates in hydrogen bonding with the incoming dTTP or dCTP (Nair et al. 2006). Since Poli is highly inefficient at extending synthesis from the T or C inserted opposite εdA, the extension reaction would require another TLS Pol and biochemical studies have indicated that Polζ can extend synthesis from the εdA·dT or εdA·dC base pair (Nair et al. 2006).

Here we identify the TLS Pols that promote replication through the EdA adduct in human cells and show that replication through this adduct is mediated via three genetic pathways. As expected from biochemical and structural studies, Polι and Polζ function together in one pathway; however, contrary to biochemical and structural observations indicating a proficiency of Poli for misincorporating C opposite εdA, the Polι/Polζ pathway mediates highly error free TLS opposite this adduct in human cells. Rev1 polymerase activity contributes to a low level of TLS that is mutagenic; in this role, Rev1 functions independent of its scaffolding role with Poli in the Poli/Polζ pathway. Polθ, a member of A-family Pols, promotes replication through εdA via a third pathway. Although biochemical studies show that purified Pol0 conducts highly error-prone TLS by incorporating an A opposite εdA, in human cells Polθ mediates predominantly error-free TLS opposite this adduct. We discuss the implications of this marked discrepancy and suggest that opposite DNA lesions such as εdA, Polθ active site is actively reconfigured in human cells to carry out predominantly error-free TLS.

Results and Discussion

Requirement of Poli/Pol ζ and Pol θ for Replication through the εdA adduct in human cells

To identify the TLS Pols required for replicating through the EdA adduct, we analyzed the effects of siRNA depletion of TLS Pols individually and in combinations (Supplemental Fig. S2) on TLS frequencies resulting from replication through the lesion present on the leading or the lagging strand template of the SV40 based duplex plasmid. TLS opposite the εdA adduct carried on the leading strand template in normal human fibroblasts (HFs) and treated with control (NC) siRNA occurs with a frequency of ~25% and TLS frequency was not affected in cells depleted for Poln or Polk, indicating that these Pols play no significant role in TLS opposite this adduct (Table 1). In contrast, TLS frequency was reduced to ~14% in Poli-depleted cells. A similar reduction in TLS frequency occurred upon depletion of the Rev3 or the Rev7 subunit of Polζ, and depletion of Polθ reduced TLS frequency to

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~17% (Table 1). The observation that TLS frequency remained the same in cells codepleted for Poli with Rev3 or Rev7 as that in cells depleted for any of these Pols alone (Table 1) indicated that Poli and Polζ function together in one TLS pathway. In contrast, codepletion of Poli with Polθ or of Rev3 or Rev7 with Polθ caused a drastic reduction in TLS frequency to ~4% (Table 1), indicating that Polθ functions independently of Poli and Polζ and that TLS through the εdA adduct is mediated by two separate pathways dependent on either Poli/Polζ or Polθ. We verified this conclusion for TLS opposite εdA present on the lagging strand template (Table 1).

Noncatalytic and catalytic roles of Rev1 in TLS opposite εdA

In human cells, Rev1 functions as an indispensable noncatalytic scaffolding component of Y-family Pols (Yoon et al. 2015). Since ~15% of total TLS persists in HFs codepleted for Pol θ with Pol $_{1}$ or Pol ζ (Table 1), we considered the possibility that in addition to its role as a noncatalytic scaffolding component of Poli in the Poli/Pol\(\zeta\) pathway, Rev1 contributes to TLS as a DNA polymerase and in this role it functions independently of Poli. To test for this possibility, we first determined whether there was evidence for Poli-dependent and Poli-independent roles of Rev1, and analyzed TLS opposite ϵdA in wild-type (WT), Rev1^{-/-} (Yoon et al. 2015), and $Pol\theta^{-/-}$ (Yoon et al. 2019) mouse embryonic fibroblasts (MEFs) depleted for different TLS Pols (Supplemental Fig. S2; Supplemental Table S1). In WT MEFs, TLS opposite edA occurs with a frequency of \sim 22% and TLS is reduced to \sim 8% in Rev1^{-/-} MEFs treated with NC siRNA or depleted for Poli or Pol². The epistasis of Rev1 over Polι in the Polι/Polζ pathway is consistent with a scaffolding role of Rev1 with Poli. To unravel the Poli-independent role of Rev1, we examined TLS in Polθ^{-/-} MEFs depleted for Polι or Polζ, since then only the Poli/Polζ-independent role of Rev1 would remain functional. Our observation that TLS frequency is reduced to ~3.5% in Pol $\theta^{-/-}$ MEFs depleted for Poli or Pol ζ strongly suggested that this residual TLS is mediated by the Poli/ Pol\(\zeta\)-independent role of Rev1. Furthermore, the almost abolition of TLS in $Pol\theta^{-/-}$ MEFs depleted for Rev1 or in Rev1^{-/-} MEFs depleted for Polθ provided confirmatory evidence for the Poli-dependent and Poli-independent Rev1 roles.

To determine whether Rev1 polymerase function was required for its Poli-independent role, we examined TLS in HFs expressing siRNA-sensitive WT Revl or the siRNA-resistant form of either the WT or the catalytically inactive Rev1 D570A, E571A mutant. TLS in cells depleted for Rev1 and carrying the vector control or the siRNAsensitive WT Rev1 was reduced to ~9% as compared to ~25% in control siRNA-treated cells (Supplemental Table S2). Expression of the siRNA-resistant WT Rev1 restored TLS frequency nearly to normal levels (~23%), while expression of siRNA-resistant D570A, E571A catalytic mutation reduced TLS to ~20% (Supplemental Table S2). This reduction in TLS frequency closely resembles the reduction in TLS frequency that occurs in HFs codepleted for Poli and Pol θ (Table 1) or in Pol $\theta^{-/-}$ MEFs depleted for Poli (Supplemental Table S1). This result suggested that Rev1 polymerase activity accounts for a small proportion of total TLS opposite edA and that this TLS operates independently of Rev1's scaffolding role with Poli, which will remain intact in Rev1 catalytic mutant. To further ascertain the contribution of Rev1 polymerase activity to TLS, we examined the effect of Rev1 catalytic mutation on TLS opposite εdA in Rev1^{-/-} MEFs. In Řev1^{-/-} MEFs expressing WT Rev1, TLS occurred at a frequency of ~19% and TLS was reduced to ~16% in these MEFs expressing catalytic mutant Rev1 (Supplemental Table S3). This result reinforces the evidence that Rev1 polymerase activity contributes to a relatively small proportion of total TLS opposite edA. Overall, from analyses of TLS in WT HFs, WT MEFs, Rev1^{-/-} MEFs, and Pol θ ^{-/-} MEFs, we conclude that TLS opposite EdA is mediated by two major Polι/Polζ- and Polθ-dependent pathways, respectively, and by a relatively minor Rev1 polymerase-dependent pathway (Table 1; Supplemental Tables S1-S3).

Requirement of Pol θ polymerase activity for TLS opposite εdA in human cells

Human Polθ is a 290 kDa protein comprised of an N-terminal ATPase/helicase domain, a large central domain, and a C-terminal polymerase domain that shares homology with A-family DNA Pols such as *Escherichia coli*

Table 1. Effects of siRNA knockdown of TLS polymerases on the replicative bypass of the εdA lesion carried on the leading or lagging strand template in HFs (GM637)

siRNA		Leading strand	Lagging strand				
	Number of Kan ⁺ colonies	Number of blue colonies among Kan ⁺	TLS (%)	Number of Kan ⁺ colonies	Number of blue colonies among Kan ⁺	TLS (%)	
NC	659	168	25.5	502	116	23.1	
Poln	623	146	23.4	460	108	23.5	
Polĸ	658	161	24.5	403	96	23.8	
Polı	589	80	13.6	367	48	13.1	
Rev3	615	82	13.3	352	38	10.8	
Rev7	308	40	13.0	401	45	11.2	
Polθ	612	102	16.7	428	60	14.0	
Polı + Rev3	623	78	12.5	394	51	12.9	
Polı + Rev7	412	49	11.9	294	34	11.6	
Polι + Polθ	674	26	3.9	408	16	3.6	
Rev3 + Polθ	236	9	3.8	426	18	4.2	
Rev7 + Polθ	405	15	3.7	314	11	3.5	

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Pol I (Yousefzadeh and Wood 2013). We have shown previously that Polθ comprised of residues 1708–2590 performs proficient TLS opposite thymine glycol in human cells (Yoon et al. 2014) and provide evidence here that Polθ (1708–2590) is sufficient for TLS opposite εdA. Whereas TLS in control siRNA-treated HFs occurs with a frequency of ~25%, this frequency declines to ~15% in cells depleted for genomic Polθ and carrying either an empty vector or one expressing siRNA-sensitive WT Polθ (1708–2590) (Supplemental Table S4). Expression of an siRNA-resistant WT Polθ (1708–2590), however, restores normal TLS levels in HFs depleted for genomic Polθ, confirming that the C-terminal polymerase domain is sufficient for Polθ-dependent TLS opposite the εdA lesion. TLS was reduced to ~15% in HFs expressing the siRNAresistant Polθ (1708–2590) D2540A, E2541A mutant protein defective in DNA synthesis, indicating that Polθ polymerase activity is required for its role in TLS opposite εdA (Supplemental Table S4). We confirmed the requirement of Polθ polymerase activity for TLS opposite εdA in $Pol\theta^{-/-}$ MEFs (Supplemental Table S5).

The $Pol_i/Pol\zeta$ pathway conducts error-free TLS opposite εdA in human cells

TLS opposite εdA incurs a high level of mutagenesis (Table 2). In control (NC) siRNA-treated cells, $\sim 16\%$ of Kan^+ blue colonies derived from TLS opposite εdA carried on the leading strand template harbored a mutation that resulted from the incorporation of primarily a C, but also of an A or a G opposite εdA . Of the incorrect nucleotides, C was incorporated at a frequency of $\sim 11\%$, whereas the A and G nucleotides were incorporated at a combined frequency of $\sim 5\%$ (Table 2). As expected from the lack of requirement of Pol η or Pol κ for TLS opposite εdA , the spectrum and frequency of mutagenic TLS opposite this adduct was unchanged upon their depletion. Importantly, depletion of Pol η , Rev3, or Rev7 raised the frequency of mutagenic

TLS to ~27% and Pol θ depletion reduced mutagenic TLS to ~10% (Table 2). These results as well as analyses of mutagenic TLS opposite ϵ dA carried on the lagging strand template indicated that Pol ℓ Pol ℓ -dependent TLS operates in an error-free manner, whereas Pol θ -mediated TLS is error-prone.

To get an estimate of the overall contributions of the Polı/Polζ and Polθ pathways to error-free and mutagenic TLS, respectively, we pooled the mutation data for the two DNA strands. Overall, mutagenic TLS opposite εdA in WT HFs occurs with a frequency of ~14%, this frequency rises to ~27% in cells depleted for Polι or Polζ, and declines to ~9% in Polθ-depleted cells (Table 2). Whereas incorporation of C occurs with a frequency of ~10% in control siRNA-treated cells, it rises to ~20% in cells depleted for Polι or Polζ and declines to ~5% in Polθ-depleted cells. These data suggested that Polθ-mediated TLS contributes to C misincorporation opposite εdA and raised the possibility that Rev1 polymerase activity contributes to mutagenic TLS that persists in Polθ-depleted cells.

The DNA polymerase activities of $Pol\theta$ and Rev1 account for error-prone TLS opposite εdA

To test whether the Rev1 polymerase activity contributes to mutagenic TLS and to determine whether Rev1 and Polθ polymerase activities provide alternative routes of mutagenic TLS, we analyzed the effects of mutations in active site residues in their polymerase domains on mutagenic TLS opposite ϵdA . As shown in Table 3, in Polθ-depleted cells expressing siRNA-sensitive WT Polθ, $\sim 10\%$ of TLS products harbor mutations, and the frequency of mutagenic TLS rises to $\sim 16\%$ in cells expressing siRNA-resistant WT Polθ, suggesting that $\sim 6\%$ of mutations result from Polθ-mediated TLS. Expression of the siRNA-resistant catalytic mutant of Polθ also reduced mutation frequency to $\sim 10\%$, indicating that Polθ's polymerase activity is required for its role in mutagenic TLS. In Rev1-depleted cells

Table 2. Effects of siRNA knockdowns of TLS polymerases on mutation frequencies and nucleotides inserted opposite εdA carried on the leading or lagging strand template in HFs (GM637)

-dA containing DNIA	siRNA	Number of <i>Kan</i> ⁺ blue colonies sequenced	Nucleotide inserted				
edA-containing DNA strand			A	G	С	T	Mutation frequency (%
Leading strand	NC	220 (35) ^a	7	3	25	185	15.9
	Polη	164 (25)	3	2	20	139	15.2
	Polκ	166 (26)	3	2	21	140	15.7
	Polı	160 (41)	5	6	26	119	25.6
	Rev3	260 (68)	13	8	47	192	26.2
	Rev7	96 (28)	5	2	21	68	29.2
	Polθ	196 (19)	3	5	11	177	9.7
Lagging strand	NC	170 (20)	2	2	16	150	11.8
	Polη	96 (11)	2	2	7	85	11.5
	Poli	188 (50)	5	1	44	138	26.6
	Rev3	96 (26)	4	0	22	70	27.1
	Rev7	104 (32)	5	0	27	72	30.8
	Polθ	180 (13)	1	3	9	167	7.2
Leading or lagging strand	NC	390 (55)	9	5	41	335	14.1
	Polı	348 (91)	10	7	74	257	26.1
	Rev3	460 (126)	22	8	96	334	27.4
	Rev7	200 (60)	10	2	48	140	30.0
	$Pol\theta$	376 (32)	4	8	20	344	8.8

^aNumber of colonies where TLS occurred by insertion of a nucleotide other than T are shown in parentheses.

Table 3. Effect of catalytically active (WT) Polθ, catalytically inactive D2540A E2541A mutant Polθ, catalytically active (WT) Rev1, or catalytically inactive D570A E571A mutant Rev1 on mutation frequencies and nucleotides inserted opposite εdA carried on the leading strand DNA template in HFs (GM637)

	Vector expressing	Number of Kan ⁺ blue colonies sequenced	Nucleotide inserted				Montalian	T TI C 1
siRNA			A	G	С	Т	Mutation frequency (%)	Error-prone TLS pathway that remains active
Polθ	WT-Polθ	96 (10) ^a	2	1	7	86	10.4	Rev1 Pol
Polθ	siR ^b -WT-Polθ	96 (15)	3	1	11	81	15.6	Rev1 Pol, Polθ
Polθ	siR-mutant Polθ	90 (9)	2	0	7	81	10.0	Rev1 Pol
Rev1	WT-Rev1	96 (7)	2	1	4	89	7.3	Polθ
Rev1	siR-WT-Rev1	96 (16)	3	2	11	80	16.7	Rev1 Pol, Polθ
Rev1	siR-mutant Rev1	88 (7)	3	0	4	81	8.0	Polθ
Rev1 + Polı	siR-mutant Rev1	80 (6)	2	0	4	74	7.5	Polθ
$Rev1 + Pol\theta$	siR-mutant Rev1	96 (0)	0	0	0	96	0.0	Neither

^aNumber of colonies where TLS occurred by insertion of a nucleotide other than T are shown in parentheses.

expressing siRNA-sensitive WT Rev1, mutagenic TLS occurs at a frequency of \sim 7%, and expression of the siRNAresistant WT Rev1 raises the frequency of mutagenic TLS to ~17% (Table 3). This result indicated the requirement of Rev1 for mutagenic TLS. To establish that Rev1 polymerase activity was required for mutagenic TLS and that Rev1 functions in this role independent of Poli, we expressed siRNA-resistant Rev1 catalytic mutant in Rev1-depleted cells or in cells codepleted for Rev1 and Poli (Table 3, items 6 and 7). In both cases, mutagenic TLS was reduced to 8%, confirming the Poli-independent role of Rev1 polymerase in mutagenic TLS. The observation that codepletion of Rev1 and Pol θ in cells expressing siRNA-resistant Rev1 catalytic mutant causes a complete inhibition of mutagenic TLS (Table 3, last item) supports the conclusion that Rev1 polymerase and Polθ polymerase activities provide alternative routes for mutagenic TLS opposite εdA (Table 3). Since no mutations occur in cells lacking Polθ and Rev1 polymerase activity but retaining the Rev1 scaffolding function, where only the Pol₁/Polζ pathway would remain functional, Polι/Polζ-dependent TLS must operate in an error-free manner (Table 3, last item).

To further ascertain the contributions of Rev1 polymerase-dependent and Polθ-dependent pathways to mutagenic TLS and to verify the requirement of Poli for error-free TLS in the Pol_ι/Polζ pathway, we analyzed the mutation spectrum of TLS products in WT and Polθ^{-/-} MEFs, and in Rev1^{-/-} MEFS lacking or expressing the catalytic mutant Rev1 protein (Supplemental Table S6). The effects of Polθ and Rev1 knockouts on the frequency and mutation spectrum of TLS products are remarkably similar to that in HFs depleted for these Pols (Table 3) and the results that no mutations are recovered in Rev1^{-/-} MEFs expressing the catalytic mutant Rev1 protein and depleted for Polθ (Supplemental Table S6) provide confirmatory evidence that Rev1 polymerase and Polθ provide alternate pathways of mutagenic TLS, and that the Polι/Polζ pathway, which would remain functional in these MEFs, operates in an error-free manner.

Biochemical analysis of Pol θ polymerase activity for TLS opposite εdA

For these studies, we examined DNA synthesis by Pol θ across from either an undamaged A or ϵ dA. Whereas oppo-

site an undamaged A template Pol θ inserts a T but also a C or a G (Fig. 1, lanes 1–5), opposite &A Pol θ primarily inserts an A (Fig. 1, lanes 9,4,19). Although Pol θ can insert each of the four dNTPs opposite &A, importantly, in the presence of all four dNTPs, dATP is preferentially inserted (Fig. 1, lane 10). Since dATP was preferentially incorporated opposite &A in a template in which the downstream 5′ template nucleotide was a T residue, we determined whether Pol θ used a frameshift mechanism to incorporate dATP opposite the downstream template T rather than opposite &A. To examine this, we used templates containing edA that harbor either an A or a G as the next templating

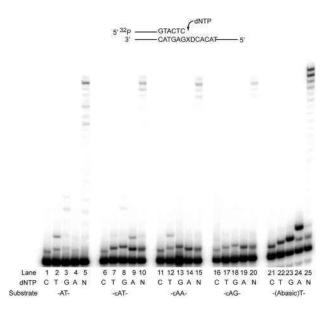


Figure 1. Nucleotide incorporation opposite A or εdA by Polθ. 0.5 or 5 nM Polθ was incubated with 10 nM DNA substrate and 25 μM of either dGTP, dATP, dTTP, dCTP, or all four dNTPs for 5 min at 37° C. Reactions containing a single or all four dNTPs [N] are indicated. The DNA substrate used in lanes 1-5 harbor undamaged template A at the primer terminus, and reactions contained 0.5 nM Polθ. The substrate in lanes 6-20 harbored εdA at the primer terminus followed by either T (lanes 6-10), A (lanes 11-15), or G (lanes 16-20) residue, indicated by D in the template sequence. Synthesis opposite an abasic site is shown in lanes 21-25. Reactions in lanes 6-25 were all carried out with 5 nM Polθ. X in the template sequence indicates the position of undamaged A, edA, or an abasic site.

 $^{^{}b}(siR)$ siRNA-resistant.

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residue downstream from the lesion (Fig. 1, lanes 11–20). In each case, an A was the best incorporated nucleotide opposite ϵdA , suggesting that Pol θ is not frameshifting the template and using the downstream nucleotide, for if it were, then the pattern of insertion would be different for each substrate and a preference for the W–C partner of the downstream nucleotide would be observed.

Pol θ exhibits a high proficiency for replicating through an abasic site by inserting an A opposite it and by extending synthesis (Fig. 1, lanes 24,25; Seki et al. 2004). Although Pol θ is more efficient in performing TLS opposite an abasic site than opposite ϵ dA, the similar pattern of nucleotide incorporation opposite the two DNA lesions (Fig. 1) suggests that the ϵ dA adduct becomes extrahelical and Pol θ incorporates an A opposite an abasic site-like mode.

Biochemical analysis of Rev1 polymerase activity for TLS opposite εdA

Rev1 specifically incorporates dCTP opposite template G (Nelson et al. 1996: Haracska et al. 2002). In the Rev1 active site, template G, and the incoming dCTP do not pair with each other; instead, the template G residue is evicted from the DNA helix and makes hydrogen bonds via its Hoogsteen edge with the amino acids in the G loop of Rev1, while an Arg residue in Rev1 forms hydrogen bonds with the incoming dCTP (Nair et al. 2005; Swan et al. 2009). Rev1 favors nucleotide incorporation opposite template G over other nucleotides because the G loop makes specific hydrogen bonds with the Hoogsteen edge of templating G. Incorporation of dCTP opposite template A is much less favorable, likely due to the presence of the N⁶ H-bond donor on adenine which would sterically hinder binding by the G loop. Since εdA lacks the N⁶ amino group (Supplemental Fig. S1A), it would not sterically clash with the G loop. Accordingly, we found that under identical conditions, nucleotide incorporation opposite edA is better than opposite template A (Supplemental Fig. S3). In fact, yeast Rev1 incorporates dCTP opposite edA with a catalytic efficiency only approximately fivefold less than template G, whereas opposite template A, yeast Revl is ~200-fold less efficient (data not shown). This proposed better binding of \(\epsilon\) dA by the Rev1 G loop over template A would also account for the incorporation of dGTP and dTTP mispairs opposite edA that is not observed opposite template A (Supplemental Fig. S3, lanes 1,3 vs. 6,8,11,13,16,18). Since in the presence of all four dNTPs (Supplemental Fig. S3, lanes 10,15,20), Rev1 preferentially incorporates dCTP, dCTP is incorporated opposite edA with the highest catalytic efficiency.

Pathways for replicating through εdA in human cells

Based upon our observations in HFs, and in WT, $Pol\theta^{-/-}$, $Rev1^{-/-}$ MEFs, we conclude that replication through the ϵdA adduct is mediated via two Rev1-dependent TLS pathways in which Rev1 functions as a noncatalytic component of Poli in the Poli/Pol ζ pathway and as a DNA polymerase that functions independently of the Poli/Pol ζ pathway and via a third pathway dependent on Pol θ (Supplemental Fig. S4). Poli/Pol ζ -dependent TLS operates in an error-free manner, Rev1 polymerase activity makes a relatively minor contribution to TLS and it acts in an error-prone manner, and Pol θ polymerase activity provides the alternative route of mutagenic TLS.

Role of Poli/Pol ζ -dependent TLS in error-free replication through ϵdA in human cells

Although structural studies have shown that Poli can accommodate dTTP or dCTP opposite edA via Hoogsteen base pairing, and biochemical studies have shown that Poli incorporates a T opposite edA with only an approximately fourfold higher catalytic efficiency than a C (Nair et al. 2006), our genetic studies reveal that Poli-dependent TLS opposite this lesion operates in an error-free manner in human cells. In the Polι active site, εdA is pushed into a syn conformation and it forms a Hoogsteen base pair with the incoming T or C residue (Nair et al. 2006). While the ability of Polito push the adduct into the syn conformation explains its proficiency for TLS opposite εdA, it does not explain how Poli avoids C incorporation in human cells. To explain the high fidelity of Poli opposite EdA in human cells, we suggest that TLS Pols function as a component of a multiprotein ensemble and that their fidelity is actively regulated in such an ensemble by protein-protein interactions and posttranslational modifications. A similar mechanism would account for predominantly errorfree replication by TLS Pols through other DNA lesions (Yoon et al. 2009, 2010, 2017, 2018; Conde et al. 2015).

Reconfiguration of Pol θ active site opposite εdA in human cells

Similar to other A family Pols, Pol θ incorporates nucleotides opposite undamaged A, G, C, or T templates via W–C base pairing. Since ϵ dA disrupts W–C base pairing, purified Pol θ could replicate through this adduct by pushing it out of the DNA helix into an abasic-like mode, then inserting an A opposite the adduct site and extending synthesis. The feasibility of this scenario is suggested from the proficient ability of Pol θ to replicate through an abasic site where it inserts an A opposite the abasic site and then extends synthesis. Structural studies with Pol θ have verified its ability to insert an A opposite an abasic site (Zahn et al. 2015).

Even though Polθ contributes to error-prone TLS opposite εdA in human/mouse cells, in both HFs and MEFs, it incorporates a T at a frequency of ~92%, a C at ~5%, and an A at ~3% (Table 3; Supplemental Table S6). Thus in spite of the propensity of purified Pol θ for incorporating an A opposite εdA, Polθ-mediated TLS opposite this adduct is predominantly error-free in human cells. Polθ could accomplish this by pushing edA into a syn conformation and by forming a Hoogsteen base pair with the incoming T. The low frequency of C insertion could also occur by similar means. Although in its potential to form a Hoogsteen base pair between \(\varepsilon \) dA in \(syn \) conformation and an incoming T or C in *anti* conformation Polθ would resemble Poli, the two Pols would differ in a number of ways. Poli has a preformed active site which enables it to similarly position an undamaged A or an edA in the syn configuration; hence, Poli would adopt a similar mechanism for performing TLS in human cells as it portrays in biochemical assays. In striking contrast, Polθ would need to adopt entirely different means for conducting TLS opposite εdA in human cells than those adopted by purified Pol θ .

To explain the adoption of different TLS mechanisms by $Pol\theta$ in human cells vs in biochemical assays with purified enzyme, we suggest that $Pol\theta$ functions in TLS in human cells as a component of a multiprotein ensemble and that protein–protein interactions and posttranslational

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modifications in that ensemble actively modulate Pol θ active site such that the ϵdA adduct is pushed and stabilized in a syn conformation, allowing for Hoogsteen base pairing primarily with the T. Thus, whereas protein–protein interactions in the Pol θ -containing multiprotein ensemble would actively reconfigure Pol θ active site for Hoogsteen base pairing opposite ϵdA enabling it to conduct relatively high fidelity TLS in human cells, in Pol θ with its preformed active site, the overall mechanism of Hoogsteen base pairing would stay the same in the multiprotein ensemble in human cells as with purified Pol but its fidelity opposite ϵdA will be greatly enhanced in human cells.

Materials and methods

Construction of edA plasmid vectors and translesion synthesis assays

The 16-mer oligonucleotides containing ϵdA , purchased from the Midland Certified Reagent Company, Inc., and the in-frame target sequence of lac Z' gene in the resulting vectors are shown in Supplemental Figure S1B. The WT kanamycin gene (Kan^*) was placed on the same DNA strand as ϵdA and Lac Z' in this DNA strand is in-frame and functional for β -gal. The opposite DNA strand harbors an Spel restriction site containing a +1 frame-shift, which makes it nonfunctional for β -gal. This DNA strand carries the Kan^- gene. The detailed methods for construction of lesion containing SV40 duplex plasmid, for assays for translesion synthesis, and for mutation analyses of TLS products have been published previously (Yoon et al. 2009, 2010).

Protein expression and purification

Rev1 core (amino acid residues 330–883) and Polθ core (amino acid residues 1708–2590) proteins were each expressed and purified from yeast as fusion proteins harboring an N-terminal Glutathione-S transferase (GST) tag as described (Johnson et al. 2006). Rev1 and Polθ proteins were expressed from plasmids pBJ1228 and pPOL507, respectively. The GST tags were removed by prescisson protease during purification.

DNA polymerase assays

Proteins were assayed using the standard DNA polymerase reaction conditions (Johnson et al. 2006). The DNA substrate consisted of the 52mer temple 5′-TTCGTATAATGCCTACACDXGAGTACCGGAGCATCGTCGT GACTGGGAAAAC-3′, where D indicates either G, A, or T and X indicates either an undamaged A or sdA annealed to the 32mer $^{32}\mathrm{P}$ radiolabeled primer 5′-GTTTTCCCAGTCACGACGATGCTCCGGTACTC-3′. Reactions (5 $\mu\mathrm{L}$), carried out for 5 min at 37°C, contained 10 nM DNA substrate, 25 $\mu\mathrm{M}$ dNTP and protein concentrations as indicated in the figure legends. Reaction products were separated by 15% TBE PAGE containing 8 M urea as described, and visualized by phosphorimaging on a Typhoon FLA 7000 (GE Healthcare).

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Author contributions: J.H.Y. performed the genetic experiments and analyzed the data; R.E.J. performed biochemical experiments and analyzed the data; L.P. and S.P. designed and coordinated the study; J.H.Y., R.E.J., L.P., and S.P. wrote the paper.

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CORRIGENDUM

Genes & Development 33: 282–287 (2019)

Corrigendum: DNA polymerase θ accomplishes translesion synthesis opposite $1,N^6$ -ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satya Prakash

In Supplemental Figure S2 in the above article, we have been unable to confirm that the Western blots in panels A–C were assembled correctly. Because of our concerns about the accuracy of the data in the Western blots, we are presenting a new set of verified experiments in the new Supplemental Figure S2, which can be found in the Revised Supplemental Material online. This change in no way affects any of the results or conclusions of this study. The authors apologize for this error.

doi: 10.1101/gad.334946.119



DNA polymerase θ accomplishes translesion synthesis opposite 1,N⁶ -ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, et al.

Genes Dev. 2019, 33: originally published online February 26, 2019 Access the most recent version at doi:10.1101/gad.320531.118

http://genesdev.cshlp.org/content/suppl/2019/02/26/gad.320531.118.DC1 Supplemental http://genesdev.cshlp.org/content/suppl/2019/12/26/gad.320531.118.DC2 Material

Corrigendum: DNA polymerase _ accomplishes translesion synthesis opposite 1,N6-ethenodeoxyadenosine with a remarkably high fidelity in human cells **Related Content**

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, et al. Genes Dev. January, 2020 34: 146

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From: Connell, Laureen <connell@cshl.edu>
Sent: Wednesday, October 23, 2019 2:36 PM

To: Prakash, Louise Subject: RE: Corrigendum

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Louise,

An ai file is fine as long as the file contains an image of the entire gel with all of the lanes. We need this to see where the lanes came from and how they are being corrected.

Thank you,

Laureen

From: Prakash, Louise <loprakas@UTMB.EDU> **Sent:** Wednesday, October 23, 2019 3:23 PM **To:** Connell, Laureen <connell@cshl.edu>

Subject: RE: Corrigendum

Dear Laureen,

I assume that original data means original western blots and not just original western blots copied and pasted into adobe illustrator to show what was cropped for use in the final figure, is that correct?

Thanks, Louise

From: Connell, Laureen <<u>connell@cshl.edu</u>>
Sent: Wednesday, October 23, 2019 2:19 PM
To: Prakash, Louise <<u>loprakas@UTMB.EDU</u>>

Subject: RE: Corrigendum

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Louise,

That sounds fine. If it is easier you can send the files via dropbox link.

Best,

Laureen

From: Prakash, Louise < loprakas@UTMB.EDU Sent: Wednesday, October 23, 2019 3:17 PM To: Connell, Laureen < connell@cshl.edu>

Subject: RE: Corrigendum

Dear Laureen,

I'm putting together the materials you've requested and arranging them so that it will be easy for you to compare the original data with the final figures. I'll send them to you as soon as I've completed putting them together.

The files will be quite large so I may have to send the material in several emails.

Thank you very much.

Louise

Louise Prakash, Ph.D.
Professor, Biochemistry and Molecular Biology
Department of Biochemistry and Molecular Biology
University of Texas Medical Branch
6.104 Medical Research Building
301 University Blvd.
Galveston, TX 77555-1061

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

From: Connell, Laureen < connell@cshl.edu > Sent: Wednesday, October 23, 2019 10:38 AM To: Prakash, Louise < loprakas@UTMB.EDU >

Subject: Corrigendum

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Prakash,

Thank you for your email. Please email me your original data for Figure S2, with an explanation for the incorrect assembly of the figures and your proposed new figures. Please also send a draft of your proposed corrigendum. If you require any assistance with the wording, please let me know. Terri and I will review everything you send and I'll get back to you as soon as I can.

Best wishes,

Laureen

Laureen Connell, Ph.D.
Senior Editor, *Genes & Development*Senior Editor, *Molecular Case Studies*1 Bungtown Rd
Cold Spring Harbor, NY 11724

From: Garite, Bibi <garite@cshl.edu> On Behalf Of Genes & Development

Sent: Tuesday, October 22, 2019 5:07 PM **To:** Connell, Laureen <<u>connell@cshl.edu</u>>

Subject: FW: Corrigendum

From: Prakash, Louise [mailto:loprakas@UTMB.EDU]

Sent: Tuesday, October 22, 2019 5:02 PM

To: Genes & Development < genesdev@cshl.edu>

Cc: Garite, Bibi <garite@cshl.edu>

Subject: FW: Corrigendum

Dr. Lauren Connell Senior Editor G&D

Dear Dr. Connell,

It has come to our notice that in our recent publication Yoon et al (2019) G&D 33:282-287), western blots in Supplemental Figure S2 were assembled incorrectly. We would like to replace Sections A, B, and C of Supplemental Figure S2 with a new figure for which the accuracy of each component used for compilation of the western blots has been carefully confirmed. Even though the replacement of Supplemental Figure S2 with the new figure does not change any of the information in the published figure, we think it important to publish the corrected figure as a corrigendum. We wish to stress that this change in no way affects any of the results or conclusions of this study.

Please let me know whether to send you the new figure with only Sections A, B, and C, or whether the new figure should also include Section D which shows RT-PCR analyses.

Thank you very much, Louise Prakash

Louise Prakash, Ph.D.
Professor, Biochemistry and Molecular Biology
Department of Biochemistry and Molecular Biology
University of Texas Medical Branch
6.104 Medical Research Building
301 University Blvd.
Galveston, TX 77555-1061

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

From: Garite, Bibi < garite@cshl.edu > On Behalf Of Genes & Development

Sent: Tuesday, October 22, 2019 9:50 AM **To:** Prakash, Louise < loprakas@UTMB.EDU >

Subject: Corrigendum

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Louise,

I spoke with the Senior Editor, Laureen Connell, and she asked if you could send an email explaining the error in Figure S2. Then she will write back and let you know what you should do.

Many thanks,

Bibi

Bibi Garite, Administrative Assistant Genes & Development Cold Spring Harbor Laboratory Press 500 Sunnyside Boulevard Woodbury, NY 11797

Phone: 516 422 4015 Fax: 516 422 4093

Email: genesdev@cshl.edu

Exhibit F: November 2019 letters from Drs. Satya Prakash, Louise Prakash, and Jung-Hoon Yoon



Subject: Genes & Development paper November 5, 2019

Dear Committee:

At the outset, I categorically state that I had no knowledge of any issues with the western blots (WBs) shown in Supplemental Figure 2 and I was in no way involved in any of the aspects of constructing this figure.

I have worked closely with Hoon since he joined our group in March 2005. In my long academic career, he is one of the very best colleagues that I have worked with. Hoon has high ethical standards; he cares deeply about discovering the truth and reporting the scientific facts, and his impeccable and impressive first author contributions with us over the past 10 years attest to this fact.

I have thought long and hard about how Hoon, who is such a diligent and highly conscientious individual who repeats experiments <u>too</u> many times to assure the accuracy of his data and conclusions, could end up being responsible for mixing up the information assembled in Supplemental Figure 2. Knowing Hoon as a person and as a scientist as well as I do, knowing the difficult circumstances in which this work was being put together, and the fact that he shares all the important aspects of a project with me, regardless of how negatively that may impact the outcome of the study or its publication, and irrespective of the time he has spent on it, I can affirmatively say that there is absolutely no way that this highly distressing episode occurred because it was in any way intentional.

In the original version of the paper submitted to G&D, we had not included Supplemental Figure 2 because the observation that depletions of respective DNA Pols reduce the frequency of translesion synthesis (TLS) opposite1,N6-ethenodeoxyadenosine (ϵ dA) had provided strong genetic evidence for the effectiveness of siRNA depletions and also because we had published such evidence before. Moreover, since in the revised version, we had included the evidence generated in Rev1-/- and Polθ-/- mouse embryonic fibroblasts (MEFs) that a reviewer had asked for, it was not necessary to include a western blot (WB) figure of siRNA depletions,. Even then I decided to include a WB figure of siRNA depletions in the revised version and asked Hoon for such a figure. I believe that this unnecessary and undue burden I put upon Hoon to assemble such a figure in a short time led to errors in compilation of this figure.

Over the years, Hoon has been working almost single-handedly on a number of novel and path-breaking projects and he has been under pressures which he puts upon himself and the pressures that I put upon him. I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion. Clearly, he did not realize the degree of mental exhaustion or the mistakes he was making when he put the figure together. It is impossible for me to see that Hoon, who cares so deeply about the validity of his results and conclusions, would knowingly misrepresent a figure which has little bearing, if any, on the data shown in the paper or on the conclusions drawn. A person with intent to falsify or misrepresent data would do so for aspects which elevate the impact of the study and not something as marginal as this figure.

In reviewing all the past contributions of Hoon with us, I have become deeply aware of the immense amount of information he puts together in preparation for each paper, and of how error-free and meticulous each of his publications is. Nevertheless, to avoid the possibility of any errors in the future, I will help Hoon in verifying the accuracy of each of the items that are included in the paper. I will also make sure that Hoon is not working on a number of different projects at the same time.

Hoon has been traumatized by the fact that he is responsible for this mishap in the figure. He is a highly devoted scientist who cares deeply about the accuracy and biological relevance of his findings and over the years with us, he has been responsible for a number of pioneering studies published in a number of leading journals, including Cell, Genes & Development, PNAS, and others Moreover, Hoon has been working assiduously on a number of other important projects. I strongly believe that publication of these studies will be highly impactful and paradigm shifting for a number of DNA repair genes which play highly effective roles in protection from breast and ovarian cancers and from leukemias.

Sincerely yours,

Satya Prakash, Ph.D.

Satya Pracash

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology 6.104B Medical Research Building

Telephone: 409-747-8602 e-mail: saprakas@utmb.edu



Subject: Genes & Development paper November 13, 2019

Dear Committee,

I wish to state at the outset that I was not involved in any way in assembling the data for the gels presented in Supplementary Figure 2. My role was to combine the Supplementary Figure files given to me into one pdf file for submission to the journal, along with the text and text figures.

Both Satya and I were shocked when we learned about the allegation against Dr. Jung-Hoon Yoon, the first author of a manuscript published in Genes & Development in March of this year. It is important to understand the kind of person that Hoon is because then it becomes totally incomprehensible that Hoon could have knowingly and intentionally misrepresented the data in Supplementary Figure 2. He has been with us for the past 14 years, and during that time, I have had ample opportunity to observe the way he conducts himself in his research and how meticulous he is with his data. He is extremely honest, forthright, conscientious, and a most trustworthy, reliable, hardworking, and responsible individual. He always repeats his experiments numerous times to be as sure as one can ever be in science that the data are reproducible and that the conclusions are warranted. The quality and quantity of work that has gone into each of his publications shows that he has accomplished a phenomenal amount of work. He has single-handedly been doing the work that in other labs would be handled by a number of individuals. In fact, one of the reviewers of the recent Cell paper on which Hoon is first author said "This is a monumental work that addresses a key problem in skin cancer and elucidates the roles of $Pol\theta$ and other TLS polymerases." (Underline mine). And another reviewer wrote "These data provide unambiguous evidence of skin cancer arising in the absence of UV induced mutations. This is a paradigm-shifting finding as it questions the dogma that UV induced mutations cause skin cancer". In this paper as well as in all his other papers, Hoon has been the prime mover – being responsible for the major aspects of the study.

After going over the details with Hoon it has become clear to me that Hoon was working under tremendous pressure at the time he prepared this figure. He was asked by Satya to provide a figure of western blots showing siRNA knockdowns of the various TLS polymerases used in the study, a figure which was actually not necessary since the genetic data and TLS assay results indicated very clearly that knockdowns were very efficient. Hoon made errors because during compilation of a number of western blots, he had many gel images open at the same time, and he picked the wrong images. When Hoon realized what he had done, he was completely devastated. He blamed himself endlessly, and felt strongly that he has brought shame on himself as well as on all others associated with him. It took several days for him to recover sufficiently to be able to address with us the details of how this might have come about. He made a genuine mistake, and I cannot over-emphasize how truly remorseful he has been. This is all because he takes his scientific work very seriously.

I have gone over various ways to reduce the probability of errors arising in the future regarding confusion in identifying western blots or similar types of data. We both agree that annotating

each blot with a western blot marker pen such that the date and samples are clearly indicated will be most useful to achieve this end. In addition, applying the same code to the original file name created by the ImageQuant instrument and to the corresponding blot should avoid any ambiguity as to the identity of the blot. He will also keep a detailed record in a lab notebook where the code name will include an illustrator file of the blot and a legend indicating what is in each lane and the relevant experimental conditions used. From now on, I will carefully go over with Hoon's record keeping in this regard and II am confident that this strategy will serve to avoid mistakes in the future.

We have compiled a new Supplementary Figure 2 and have sent this figure to Genes & Development to be published as a Corrigendum. I have been corresponding with Dr. Laureen Connell, Senior Editor, Genes & Development, regarding the corrigendum and there do not seem to be any issues with replacing the figure. The emails from Dr. Connell are included with the materials provided to the committee.

Thank you for giving us the opportunity to explain the circumstances that led to mistakes in the compilation.

Sincerely yours,

Louise Prakash, Ph.D.

Louise Proposh

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology 6.104A Medical Research Building

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu



November 13, 2019

Letter of Explanations to Scientific Integrity Committee

In going over Supplementary Figure S2, I have realized that I failed to keep a record of how I had compiled this figure and it has become clear to me that I made errors in assembling this figure. I am always very concerned about the accuracy and repeatability of my data and I have been extremely upset about not being careful in assembling this figure I want to emphasize that all these mistakes are unintentional errors and I wish to explain the circumstances under which this figure was made.

I joined the Prakash lab in 2005 with a specific purpose of studying translesion synthesis (TLS) mechanisms in human cells. For this purpose, I designed a novel duplex plasmid system in which replication through a site-specific DNA lesion present on the leading or the lagging DNA strand could be analyzed methodically. For determining the contribution of various TLS polymerases (Pols), I began using siRNA depletion method as this approach avoids the complications of genetic suppression or other genetic artifacts that accompany null mutations. After over two years of effort, I established the plasmid system and optimized the efficient siRNA depletion conditions for a number of TLS Pols in human and mouse cell lines. To confirm the efficient siRNA depletion of TLS Pols in mammalian cells, I used western blot analysis and if necessary, RT-PCR. The establishment of these approaches has allowed me to systematically analyze the genetic control of TLS opposite different types of DNA lesions in human cells and these studies have been published in prestigious scientific journals.

When I prepared the Figure S2 for the Genes & Development paper, I was working under tremendous pressure of time and of having to deal with a number of different ongoing studies. Moreover, in the last year I had taken over the work of post-docs who had left the laboratory. At the same time, I was handling a rather complex paper for Cell, and when Satya wanted me to provide a new figure for siRNA depletions, because of the concern for the revision deadline, I rushed to finish the figure. I opened many files of western blot images on the computer screen and because of lack of attention and confusion, I mixed up the files and didn't double check the final figure before submission. I do realize that there is no excuse for my making these mistakes; from now on, I will be much more careful so that such mistakes never happen again.

To avoid such errors from occurring in the future, I have discussed a strategy with Louise which I plan to follow. Our laboratory uses the ImageQuant LAS4000 camera system for obtaining digital images of our western blots of other samples. The digital images are produced by exposing the blot to chemiluminescence and the system automatically names the file with the date it is created. From now on, for each file genrated by the ImageQuant, I will add a code name to each corresponding blot using a western blot marker pen so that there will be no ambiguity as to the identity of the samples in a particular blot. In addition to annotating each blot with the date and sample name, I will keep a detailed record of each blot in a notebook where every lane of the particular blot will be clearly labeled as to what sample is in each lane, what antibody was used, and any other pertinent experimental details. Blots will not be copied into adobe illustrator until they have been clearly marked. We expect that this procedure will substantially reduce the probability of error. In addition, I will consult with Louise and show her my annotation system so that there will be no confusion as to what each blot represents.

Thank you very much for considering my explanation of the circumstances that led to this unfortunate, and entirely unintentional, incident for which I take full responsibility.

Sincerely yours,

Jung-Hoon Yoon, PhD

Research Scientist

Biochemistry and Molecular Biology

6.108 Medical Research Building

Telephone: 409-747-8604; e-mail: juyoon@utmb.edu

Exhibit G: November 13, 2019 letter to Dr. Nisha Garg re western blot analyses



November 13, 2019

Dear Nisha,

In response to your email of September 17, 2019, we are providing you with the documentation of our ability to detect endogenous levels of Rev1, DNA polymerase iota, DNA polymerase kappa, DNA polymerase theta, DNA polymerase eta, and of the Rev7 subunit of DNA polymerase zeta in GM637 human fibroblasts (HFs), and to detect endogenous levels of various translesion synthesis (TLS) DNA polymerases (Pols) in mouse embryonic fibroblasts (MEFs). Importantly, the data assembled in the new Supplementary Figure S2 provide strong evidence of high efficiency of siRNA depletions of these TLS Pols in HFs and MEFs. An image of the entire gel with all the lanes was copied and pasted into Adobe Illustrator, and the region used for the final figure is indicated by a box in the gel image. We have marked each segment in the new Supplemental Figure S2 as (a1), (a2) and so on, to facilitate comparison with the corresponding ai file. The original western blots are also provided along with a list of the identity of each file.

We have sent the new Supplemental Figure to Genes & Development to be published as a corrigendum and we are providing you with all the correspondence with Dr. Laureen Connell, Senior Editor, Genes & Development. We expect the corrigendum to be published soon.

We are also providing you with our as well as Hoon's responses to this mishap.

Thank you very much.

Sincerely yours,

Louise Prakash

Satya Prakash

Experimental procedures

Western blot analysis for siRNA depletion of TLS Pols in HFs or MEFs

48h after siRNA transfection, cells were washed with PBS buffer and lysed with RIPA buffer (1x PBS, 1% IP-40, 0.5% sodium deoxycholate, 0.1% SDS). 30μg of prepared cellular extracts were separated on a 10% SDS-polyacrylamide gel and transferred to a PVDF membrane (Bio-rad). The membranes were probed with antibodies against Polη (rabbit polyclonal antibody against full length of human Polη), Polı (Bethyl Laboratories, A301-304A), Polκ (Bethyl Laboratories, A301-977A), Rev1 (Abcam, Ab5088), Rev7 (BD Biosciences, 612266), or Polθ (Abcam, Ab80906) followed by appropriate secondary antibodies conjugated with horseradish peroxidase. The signals were detected using ECL-Plus (GenDEPOT) or SuperSignal West Femto reagent (Thermo Scientific). For the loading control, anti-β-tubulin antibody (Santa Cruz Biotechnology, sc-5274) was used.

Antibody list

Antibody	SOURCE	IDENTIFIER
Rabbit polyclonal anti-Pol eta	Lab Stock (against full length Poleta)	N/A
Rabbit polyclonal anti-Pol lota	Bethyl Laboratories	A301-304A
Rabbit polyclonal anti-Pol Kappa	Bethyl Laboratories	A301-977A
Rabbit polyclonal anti-Pol theta	Abcam	Ab80906
Goat polyclonal anti-Rev1	Abcam	Ab5088
Mouse monoclonal anti-Rev7	BD Biosciences	612266
Mouse monoclonal anti-β tubulin (D-10)	Santa Cruz Biotechnology	sc-5274
Goat anti-rabbit IgG-HRP	Santa Cruz Biotechnology	sc-2004
Goat anti-mouse IgG-HRP	Santa Cruz Biotechnology	sc-2005
Rabbit anti-goat IgG-HRP	Santa Cruz Biotechnology	sc-2768



Subject: Genes & Development paper November 5, 2019

Dear Committee:

At the outset, I categorically state that I had no knowledge of any issues with the western blots (WBs) shown in Supplemental Figure 2 and I was in no way involved in any of the aspects of constructing this figure.

I have worked closely with Hoon since he joined our group in March 2005. In my long academic career, he is one of the very best colleagues that I have worked with. Hoon has high ethical standards; he cares deeply about discovering the truth and reporting the scientific facts, and his impeccable and impressive first author contributions with us over the past 10 years attest to this fact.

I have thought long and hard about how Hoon, who is such a diligent and highly conscientious individual who repeats experiments <u>too</u> many times to assure the accuracy of his data and conclusions, could end up being responsible for mixing up the information assembled in Supplemental Figure 2. Knowing Hoon as a person and as a scientist as well as I do, knowing the difficult circumstances in which this work was being put together, and the fact that he shares all the important aspects of a project with me, regardless of how negatively that may impact the outcome of the study or its publication, and irrespective of the time he has spent on it, I can affirmatively say that there is absolutely no way that this highly distressing episode occurred because it was in any way intentional.

In the original version of the paper submitted to G&D, we had not included Supplemental Figure 2 because the observation that depletions of respective DNA Pols reduce the frequency of translesion synthesis (TLS) opposite1,N6-ethenodeoxyadenosine (εdA) had provided strong genetic evidence for the effectiveness of siRNA depletions and also because we had published such evidence before. Moreover, since in the revised version, we had included the evidence generated in Rev1-/- and Polθ-/- mouse embryonic fibroblasts (MEFs) that a reviewer had asked for, it was not necessary to include a western blot (WB) figure of siRNA depletions,. Even then I decided to include a WB figure of siRNA depletions in the revised version and asked Hoon for such a figure. I believe that this unnecessary and undue burden I put upon Hoon to assemble such a figure in a short time led to errors in compilation of this figure.

Over the years, Hoon has been working almost single-handedly on a number of novel and path-breaking projects and he has been under pressures which he puts upon himself and the pressures that I put upon him. I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion. Clearly, he did not realize the degree of mental exhaustion or the mistakes he was making when he put the figure together. It is impossible for me to see that Hoon, who cares so deeply about the validity of his results and conclusions, would knowingly misrepresent a figure which has little bearing, if any, on the data shown in the paper or on the conclusions drawn. A person with intent to falsify or misrepresent data would do so for aspects which elevate the impact of the study and not something as marginal as this figure.

In reviewing all the past contributions of Hoon with us, I have become deeply aware of the immense amount of information he puts together in preparation for each paper, and of how error-free and meticulous each of his publications is. Nevertheless, to avoid the possibility of any errors in the future, I will help Hoon in verifying the accuracy of each of the items that are included in the paper. I will also make sure that Hoon is not working on a number of different projects at the same time.

Hoon has been traumatized by the fact that he is responsible for this mishap in the figure. He is a highly devoted scientist who cares deeply about the accuracy and biological relevance of his findings and over the years with us, he has been responsible for a number of pioneering studies published in a number of leading journals, including Cell, Genes & Development, PNAS, and others Moreover, Hoon has been working assiduously on a number of other important projects. I strongly believe that publication of these studies will be highly impactful and paradigm shifting for a number of DNA repair genes which play highly effective roles in protection from breast and ovarian cancers and from leukemias.

Sincerely yours,

Satya Prakash, Ph.D.

Satya Pracash

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology 6.104B Medical Research Building

Telephone: 409-747-8602 e-mail: saprakas@utmb.edu

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 139 of 514

MOU:

MOU – for the purpose of developing a research and training program

UTMB:

J. LeDuc

RECIPIENT:

Wuhan Institute of Virology

Chinese Academy of I Sciences

EXPORT CONTROL:

N/A



MEMORANDUM OF UNDERSTANDING OF COOPERATION BETWEEN WUHAN INSTITUTE OF VIROLOGY,

CHINESE ACADEMY OF SCIENCES

AND THE UNIVERSITY OF TEXAS MEDICAL BRANCH

AT GALVESTON

Wuhan Institute of Virology, Chinese Academy of Sciences, with its legal address and premises at No. 44, Xiao Hong Shan, Wuhan, Hubei Province, China 430071 (hereinafter referred to as "WIV")

AND

The University of Texas Medical Branch, with its legal address and premises at 301 University Blvd, Galveston, Texas 77550 (hereinafter referred to as "UTMB")

WIV and UTMB hereinafter also individually referred to as a "Party" or collectively as the "Parties"

The parties reached and confirmed with the Memorandum of Understanding (hereinafter referred to as "Memorandum") their consensus to establish exchanges and collaboration in areas of mutual interest and benefit.

I. GENERAL PROVISION

i) Relationship between the parties

Nothing contained herein shall be construed as establishing a relationship of agent and principal or master and servant between the parties. Each party shall have full control of its operations and undertakings and shall have full responsibility for activities and duties carried by it and on its behalf.

ii) Good faith and fairness

- a) The parties undertake to act in good faith with respect to each other's rights under the obligations and objectives of this MoU.
- b) The parties, their representatives, their researchers and personnel shall not, either during or after the term of this MoU, disclose proprietary information relating to the

undertaking by both parties and each other's operations without the consent of the other party.

c) The parties recognise the impracticality of providing for every contingency, which may arise during or after the life of the MoU and hereby agree to operate fairly and without detriment to the interests of either of them.

iii) Notices

Any notice, request or consent required or permission to be given or made pursuant to this MoU shall be in writing. Any such notice, request or consent shall be deemed to have been given or made when delivered either in person to the authorized representative at the Head Office of the party to whom communication is addressed or when sent by registered mail or by fax to such party at the following address:

For: Wuhan Institute of Virology

The Director General: Dr. Chen Xinwen

PO Box 430071

Xiao Hong Shan No.44

Wuhan, Hubei Province

The People's Republic of China

Tel: (0086)027-87199106

E-mail: chenxw@wh.iov.cn

For: The University of Texas Medical Branch

Dr. James LeDuc

301 University Blvd, 77550

Galveston, Texas

The United States

Tel:

E-mail:

Provided that a party may change its physical address and email for notice hereunder by giving the other party notice of such change pursuant to this clause.

Proof of posting or dispatch shall be deemed to be proof of receipt:

a) In the case of a letter, on the 10th day after posting

b) In the case of email, on the day immediately following the date of dispatch, but the sender has to confirm receipt of the same by the other party by telephone.

Without prejudice to the foregoing provisions, any notice shall be sent by the quickest means reasonable available.

II. OBJECTIVES OF THE COOPERATION

The objectives of the cooperation between WIV and UTMB are as follows:

- to promote the research cooperation between China and the United States for controlling infectious diseases, protecting laboratory safety and global health security;
- to deepen the training and education of all parties to this MoU; and
- to strengthen the academic and talent exchanges between the parties.

II. CONTENTS OF THE COOPERATION

To achieve these objectives, WIV and UTMB will, insofar as the means of each allow:

- promote talent and education exchanges by initiating visiting scientists and post-doctoral education programs;
- receive researchers, technicians and students of both parties for periods of training, study and/or research;
- organize symposia, conferences, short courses, workshops and meetings on research issues;
- · carry out joint research programs and apply for international grants with joint efforts;
- exchange information pertaining to developments in teaching, faculty, staff and student development and research at each institution and
- exchange the virus resources strictly for the scientific research purposes.

III. MANAGEMENT SYSTEM OF THE MOU

- i) WIV and UTMB will provide necessary supports to the MoU. If necessary the parties can communicate for asking other scientific research units in globe to participate in relevant scientific research activities in this MoU.
- ii) Each party shall designate a coordinator to oversee and facilitate the implementation of this MoU. The coordinators, working with other appropriate administrators at the respective institutions, shall have the following responsibilities:
- to promote academic collaboration at both researchers, technicians and student levels for research, training and study;
- · to act as principal contracts for individual and group activities and to plan and coordinate

all activities under this MoU within their institutions as well as with the other party;

- to distribute to each party information about the faculty, facilities, research, publications, library materials and educational resources of the other party; and
- to meet periodically to review and evaluate past activities and to work out new ideas for future cooperative agreements.

IV. INTELLECTUAL PROPERTY

Both parties do agree that:

- i) Title rights, copy rights, patent rights or any other intellectual rights in Intellectual Property belonging to either party prior to this MoU shall remain with said Party. Title rights, copy rights, patent rights or any other intellectual rights in any Intellectual Property generated from information and data collected and analyzed under the MoU shall be the property of both WIV and UTMB.
- ii) That prior to any disclosure of proprietary information by one party to the other concerning specific aspect of this collaboration, the one party may require the other to execute a confidentiality agreement.
- iii) Once WIV and UTMB are satisfied that a given discovery ("Invention") arising from a joint project under the MoU is worth protecting by a patent, the Parties will negotiate in good faith to establish the terms of an "Inter-Institutional Agreement" or IIA, or such other agreements as may be appropriate, setting forth, amongst other things, the parties' agreement on the control of patent prosecution, administration and maintenance and on the responsibility for further research, development and commercialization of the Invention and associated rights. The parties intend that the terms of any Inter-Institutional Agreement shall outline each Party's assumption of equal responsibilities in administration of any patent obtained under this MoU. Responsibility for expenses relating to registration, administration and further development and exploitation of the invention (including funds to the inventors to carry out further work to bring the invention to a stage where it can be commercially exploited, researching for commercial outlets, advertising expenses, and fees for patent attorneys) will be agreed upon by both parties. Any decision relating to the commercial exploitation or to the manner of disposal of the patent shall be made jointly taking into consideration the patent regulations of each party in particular the role of the inventor with commercialization revenues received for the Invention or the rights therein to be shared equally among the parties according to their shares in the Invention.
- iv) Material for publication or presentation arising from the joint research projects under the MoU shall be submitted for clearance to the two parties to ensure that no patentable discoveries are published prior to protection by patents.

v) Any scientific publications resulting from the collaborative research under the MoU, including scientific papers, books and proceedings of conferences, seminars and workshops will be authored jointly to reflect where relevant contributions have been made and quoting the names of authors and the two parties as well as the donor agencies if applicable.

V. FUNDING

It is understood and agreed that WIV and UTMB will each be responsible for their own expenses incurred in the performance of the collaborative research programs under this MoU. Neither party is under obligation to fund the portion of the collaborative research program conducted by the other party.

VI. ADMINISTRATION OF THE MOU

Both parties agree (that):

- a. This MoU shall be identified only as the current wish and intent of the Parties regarding the potential for developing a program agreement executed between the parties.
- b. Further agreements concerning any program shall be independent of this MOU and shall each provide details concerning the specific commitments made by each party and shall not become effective until they have been reduced to writing and executed by the duly authorized representatives of the parties.
- c. Any collaborative research agreement, or similar arrangement related to scientific development and/or discovery, shall be separately negotiated and a written agreement executed by and between the parties for each such arrangement.
- d. To work out mechanisms of reviewing and evaluating the impact of the MoU every year and at the end of the MoU duration and to monitor implementation of any on-going activities.
- e. To advice either party on available areas of collaboration and advice the Chief Executives of the institutions through a written report on the progress of the collaboration or on any need to amend or review the same.

VII. DURATION OF THE MOU

The MoU will remain in force for five (5) years at the end of which both parties will review and may renew the collaboration.

VIII. EFFECTIVE DATE

i) This memorandum shall become effective immediately from the date of the last signature by the appropriately authorized officers of each of the two institutions.

ii) This memorandum may be extended by both parties' written consent after the expiration of the MoU.

IX. MODIFICATION/AMENDMENTS

- i) Modification of the terms and conditions of this MoU may only be made by written agreement between the parties, duly signed by authorized officers of both parties and the same will be incorporated in the annexure of this Memorandum of Understanding.
- ii) Either party wishing to modify/ or amend the MoU shall give the other party two (2) months written notice of such intentions and shall send the proposed modifications/amendments within the two (2) months notice period.
- iii) The modification/amendment proposal will be discussed between the parties who will make recommendations to the Chief Executives of the institutions who will execute the modified/amended MoU.

X. SUSPENSION

- i) In the event of one party not fulfilling its part of the obligations as spelt out in this MoU and the aggrieved party is being adversely affected, the aggrieved party is at liberty to suspend the MoU with immediate effect and call for renegotiating within 7 to 21 days.
- ii) In the event of the other party not availing itself for renegotiating with the aggrieved, the aggrieved party may give the other party a notice of termination but in the meantime handle the cause of grievance/dispute in the best way possible to avoid further deterioration/harm occurring.

XI. TERMINATION

- i) Either party may terminate the MoU if the other party is in breach of terms and conditions of this MoU. The aggrieved party shall give the other party three (3) months notice of the termination of the MoU; provided that the other party has been given a one (1) month notice and the breach has not been rectified.
- ii) Either party may terminate this MoU without cause and without penalty by giving three (3) months written notice to the other Party
- iii) In the event of such termination of the MOU any on-going activity under the collaboration shall be dealt with as shall be mutually agreed by the two institutions.
- iv) Where such activity involves students, the parties shall ensure that the students shall be able to complete their studies.

v) Any gains or losses in the pursuance of the objectives of this MoU that shall have been incurred at the time of termination shall be shared in mutually agreed ratios.

XII. SETTLEMENT OF DISPUTES

- i) The parties shall use their efforts to settle amicably all disputes arising out of or in connection with this MoU and/or its interpretation hereof.
- ii) Any dispute, difference or question which may arise at any time between the parties, which cannot be settled amicably within thirty (30) days after receipt by one party of the other party's request for such amicable settlement shall be referred to the decision of a single arbitrator to be agreed upon between the two parties or in default of agreement within 14 days of each party raising such dispute.
- iii) Any party not satisfied with the arbitration, shall have the right to seek justice in the Courts of law.

XIII. INDEMNITY

The parties do agree that if a legal suit arises with regard to the management and/or administrative in-capabilities and/or lapses that may arise as a result of action or inaction on the part of the party, which may have led to either party being sued individually, jointly or severally, each party shall be responsible for its own legal fees and expenses.

XIV. EXPORT CONTROL

The parties acknowledge that this Agreement and the performance thereof are subject to compliance with any and all applicable Chinese and United States laws, regulations, or orders, including those that may relate to the export of technical data, and both Parties agree to comply with all such laws, regulations and orders, The Parties agree that if the U.S. export laws and/or those of the People's Republic of China are or become applicable, neither Party will export any Materials or information deemed Export Controlled, received under this Agreement to any countries for which the United States or Chinese government requires an export license or other supporting documentation at the time of export or transfer, unless said Party has obtained prior written authorization from the appropriate authority responsible for such matters.

XV. FORCE MAJEURE

Both parties shall be released from their respective obligation in the event of national emergency, war, prohibitive governments' regulations or of any other cause beyond the reasonable control of the parties or either of those that render the performance of this MoU impossible whereupon moneys due under this agreement shall become due and payable.

The MoU will consist of four numbered copies of equal value. Each Party will retain two copies and can make further copies as required.

XVI. CONFIDENTIALITY

- i) All cooperation and exchanges documents, data, details and materials shall be treated as confidential information by the parties.
- ii) The party may not make use of their mutual dealings for advertising purposes without the other's prior written consent.
- iii) The confidentiality obligation shall be applicable throughout the duration of this MoU and after it has been terminated. The party is entitled to ask the other to destroy and/or return the secret files, materials and equipment without any backups.

In witness whereof the parties have affixed their common seals on thisday of2017.

WUHAN INSTITUTE OF VIROLOGY, CHINESE ACADEMY OF SCIENCES

Name: Xinver Clen

Title: Director General

Place: Wuhan, China

Read and understood:

Signature of WIV Coordinator

Prof. Zhiming Yuan

THE UNIVERSITY OF TEXAS MEDICAL BRANCH

Name: Carolee A. King, J

Title: Senior VP and General Counsel

Date: 1012017

Place: UTMB Galveston, TX

Read and understood:

Signature of UTMB Investigator (Coordinator)

Dr. James W. LeDuc

Content reviewed



6.104 Medical Research Building 301 University Boulevard Galveston, TX 77555-1061 **O** 409.747.8601

March 3, 2020

Dear Dr. Garg:

This letter is in response to the Investigation Reports you sent to each of us, the Respondents, Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.-H. Y) on Feb. 6, 2020 at 4:14 PM, in which you reproduce the allegations made by the complainant of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our Genes & Development publication, vol. 33, 282-287, 2019. These letters list the members of the UTMB standing SIC involved in both the Inquiry and Investigation and the Summary Statement and Recommendations of the SIC. Given serious issues with the process and significant concerns about the content of this investigation, we object to the recommendations proposed in it, namely dismissal of Dr. Jung-Hoon Yoon from UTMB.

Let me start with our serious concerns about the process. The guidelines of the Policy and Procedure Manual on Integrity in Research (PPMIR) are very clear on the steps that need to be taken in determining the merit of allegations of misconduct; however, as documented below, the proper procedures were not adhered to in this particular case.

Since the guidelines indicate that an inquiry report, which we have not seen and suspect does not exist, should have been sent to the President, we have copied him on this communication; and since we have discussed this matter with the Chair of our Department, we have copied Dr. Mariano Garcia-Blanco as well.

Page 7, section IV E of the PPMIR, states: "During the research misconduct proceeding, the SIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for by law and UTMB policies and procedures."

We did not receive any notices during the proceedings

We list below specific examples where proper procedures were not followed, along with our comments noted in bold:

- (1) Section VI A p.10 of the PPMIR details what the written Inquiry report should contain. Among other items, it should include a summary of the inquiry process used, a list of the research records reviewed, the basis of concluding whether or not an investigation is warranted, and any comments on the draft report by the Respondent or Complainant.
 - We were not provided with any such information and were given no opportunity to comment on the inquiry report.
- (2) Section VI B on p. 10 of the PPMIR states that the SIO shall provide a copy of the inquiry report to the President and to the respondent at the same time and that the respondent has 10 calendar days to send comments to the President regarding the contents of the inquiry report.
 - We were never given a copy of the inquiry report; therefore, we were not allowed the opportunity to send our comments to the President.

(3) On p. 11 in section VI B of the PPMIR, it states that "The President will determine in writing whether an investigation is warranted."

The letters we received from you on Feb. 6, 2020 were entitled "INVESTIGATION REPORT" and state that the SIC members determined there was sufficient ground to proceed to the investigation step. This implies that several steps in the mandated process were not carried out according to the guidelines set forth in PPMIR.

(4) Once the President has determined that an investigation is warranted, in section VII C, p. 12 of the PPMIR, it states that "The President, in consultation with the SIO and other institutional officials as appropriate, will appoint an investigation committee of at least 3 members..." Thus, the SIC and the Investigation Committee are NOT the same.

The bottom of page 1 of the letters we received from you lists the names, etc. of the UTMB SIC members involved in BOTH the inquiry AND the investigation.

(5) On p. 12, in section VII C of the PPMIR, it states that "The President will notify the Respondent of the proposed committee membership to give the Respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest."

We never received any such notification. In fact, as noted above, the SIC committee performed both the inquiry and investigation reports whereas in the email of Sept. 17, 2019 at 1:25 PM, we were notified that it was an inquiry which you would like to complete in 60 days.

(6) According to p. 13, section VII E of the PPMIR, the investigation committee and the SIO must interview each Respondent and Complainant.

None of us, the respondents, were interviewed by the Investigation Committee.

(7) Section VIII. A on p. 14 provides a list of the elements that the written draft of the investigation report needs to include.

No details were provided in the investigation report.

The SIC's actions are even more troublesome in view of the fact that we had provided all the information we were asked for, as noted below.

Your email of Sept. 17, 2019 at 1:25 PM stated that "We would like to complete the inquiry in the next 60 days". In a later email that day (Sept. 17, 2019 at 3:28 PM) you wrote "Please provide us, in defense, documentation for the ability to detect endogenous level of Rev1, DNA Polymerase lota, DNA polymerase kappa in human or other cells used in the study, and original Western blots / images of the original blots, and documentation of the experiments." We, all 3 respondents: Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.H.-Y) provided you with extensive documentation of our ability to carry out these studies in our November 18, 2019 response to you. In addition, we provided the corrigendum for Supplemental Fig. 2 that has been published in Genes & Development. And in our letters (SP & LP), we pointed out the highly error-free track record of Dr. Yoon and we noted that the inclusion of Supplemental Fig. 2 had no bearing on the impact or conclusions of this study.

Between Sept 17 and Nov 18, before we sent you our letters of response, I (LP) communicated with you by telephone several times for advice on what information to include in our response. After

spending many hours examining the complainant's notebooks and comparing relevant pages to the Western Blots (WBs) he referenced, I found many discrepancies which led me to question the validity of his allegations. In the draft of my original response, I had included the following statement: "I want to point out that I spent a lot of time examining the notebooks of the individual making the complaint and I found several instances in which the points brought out by the complainant did not confirm the allegation." We (SP & I) accepted your suggestion to remove this statement because we were given the impression that it was not necessary - thinking that all you needed was the evidence you had asked for in your Sept. 17, 3:28 PM email. Therefore, we were shocked and traumatized to receive your email of February 6 with the attached Investigation Report letters, since we had not been made aware that the Inquiry Phase had progressed to the Investigation Phase.

We (LP & SP) have discussed this situation with our Chair, and respectfully request that the Guidelines of the PPMIR be followed and that the Inquiry and subsequent steps be re-initiated from the beginning. Importantly, I (LP) have uncovered that the majority of the complainant's allegations cannot be substantiated, and it is only if the Inquiry is followed in the proper order that we can discuss these issues with the SIC inquiry committee, and with the Investigation Committee, should it proceed to that stage.

The precipitous action of the SIC and its recommendations, especially the extreme one that Dr. Yoon be terminated from UTMB, without consideration of his excellent track record, path breaking publications, and his devotion to science (for a detailed explanation see our letters that were included in our Nov. 18, 2019 email to you and are attached here) have been extremely devastating to all the respondents. We also feel that no consideration was given to the circumstances under which this error occurred, for which Dr. Yoon has been extremely remorseful, and the steps we have undertaken to avoid such errors in the future (see Section §93.408 Mitigating and aggravating factors in HHS administrative actions, p. 648 of Public Health Service: Policy on Scientific misconduct 42 CFR Part 93).

Content of Allegations

In this communication, we have not addressed in detail the content of the allegations. We will comment on them at the appropriate stage and will do so in great detail.

Thank you very much.

Sincerely,

Louise Prahash

Louise Prakash

Satyr Prakash

Satya Prakash

Jung-Hoon Yoon

From: Garg, Nisha <nigarg@utmb.edu> Sent: Tuesday, March 23, 2021 4:26 PM

To: Prakash, Louise <loprakas@UTMB.EDU>; Prakash, Satya <saprakas@UTMB.EDU>

Cc: Rosemond, Valerie S. <vsrosemo@UTMB.EDU>; King, Carolee A. (Legal) <caaking@UTMB.EDU>

Subject: G&D paper

Hello Louise and Satya. I have been asked by the office of research integrity to address if the administrative actions recommended in Scientific Integrity Committee report are implemented. For this purpose, I request you to let me know the current employment status of Dr. Hoon and the lab procedures/protocols that are implemented/followed to ensure proper recording of the data and gel images in the lab.

Please send your response by Monday March 29th at the latest. Thank you

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer
Professor, Microbiology & Immunology
University of TX Medical Brench at Galveston
C: 409-747-6865; E: nigarg@utmb.edu

Prakash, Louise

From:

Prakash, Louise

Sent:

Thursday, March 25, 2021 2:27 PM

To:

Garg, Nisha

Cc:

Raimer, Ben G.; Garcia-Blanco, Mariano A.; Rosemond, Valerie S.; King, Carolee A. (Legal)

Subject:

RE: G&D paper

Attachments:

Response to Investigation Report letters

Importance:

High

Dear Nisha,

We find your communication of March 23, 2021 (4:26 PM) perplexing because we had sent you an email letter over one year ago, on March 3, 2020, documenting in great detail our serious concerns regarding the allegation of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our *Genes & Development* publication (2019, vol. 33, 282-287). In addition to sending that email and the attached materials to you, we had copied President Ben Raimer and our Chair, Dr. Mariano Garcia-Blanco. As you will note in that email (which is attached here), we expressed our concerns in detail and cited numerous examples of how procedures described in the <u>Policy and Procedure Manual on Integrity in Research (PPMIR)</u> of the University of Texas Medical Branch at Galveston had not been followed. Since we did not hear from you, we assumed that the matter had been closed. We have discussed this matter again with Dr. Garcia-Blanco and he shares our concerns.

Dr. Yoon's employment status at UTMB remains the same and he continues to make seminal contributions to translesion DNA synthesis mechanisms. Also, we stress that for each experiment we have been following very methodical and stringent procedures to ensure proper recording of the data and gel images.

Sincerely,

Louise Prakash, Ph.D.
Professor, Department of Biochemistry and Molecular Biology
I.H. Kempner Professor in Human Genetics
loprakas@utmb.edu

Satya Prakash, PhD.
Professor, Department of Biochemistry and Molecular Biology
Charles Marc Pomerat Professor in Biological Sciences
saprakas@utmb.edu

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From: Garg, Nisha <nigarg@utmb.edu> Sent: Tuesday, March 23, 2021 4:26 PM

To: Prakash, Louise < loprakas@UTMB.EDU>; Prakash, Satya < saprakas@UTMB.EDU>

Cc: Rosemond, Valerie S. <vsrosemo@UTMB.EDU>; King, Carolee A. (Legal) <caaking@UTMB.EDU>

Subject: G&D paper

Hello Louise and Satya. I have been asked by the office of research integrity to address if the administrative actions recommended in Scientific Integrity Committee report are implemented. For this purpose, I request you to let me know the current employment status of Dr. Hoon and the lab procedures/protocols that are implemented/followed to ensure proper recording of the data and gel images in the lab.

Please send your response by Monday March 29th at the latest. Thank you

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer Professor, Microbiology & Immunology University of TX Medical Branch at Galveston O: 409-747-6865; E: nigarg@utmb.edu





The University of Texas Medical Branch SCHOOL OF MEDICINE

Dr. J-H Yoon Department of Biochemistry and Molecular Biology UTMB Galveston

June 3, 2021

Reference: Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019): Allegations of Research Misconduct

Dear Dr. Yoon,

We have received your statement on March 25, 2021 (cosigned with Dr. L Prakash and Dr. S Prakash), with reference to the UTMB Scientific Integrity Committee ("SIC") Report you received dated January 2, 2020 ("SIC Report").

We have provided documents including complainant report, your statements, SIC Report, and executive decision to the Office of Research Integrity ("ORI") of the Human Health Services and have discussed your case with the Director of ORI. During this discussion with ORI, we realized that we have made a mistake in labeling the SIC Report as an Investigation Report when it should have been labeled as an Inquiry Report.

Please consider the SIC Report an Inquiry Report rather than an Investigation Report. Since it is an inquiry report, it is premature for the SIC to make recommendations, therefore please disregard Section 4 of the SIC Report entitled "Recommendations of the SIC". However, SIC findings during the inquiry phase provided sufficient evidence to move into the investigation phase.

This letter is to inform you that the SIC will perform the investigation in compliance with UTMB policies and Public Health Service regulations. We will provide you an updated copy of the UTMB policy on research misconduct. During the investigation, the SIC will review additional papers, presentations, and grants to which you might have contributed. You will have an opportunity to be interviewed by the members of the SIC and present material in your defense. Other members of your lab including your PI will also have the opportunity to provide testimony on your behalf.

Please do not hesitate to contact me for any information that you may need in this regard.

Sincerely

Nisha Jain Garg PhD MBA Scientific Integrity Officer

Professor, Microbiology & Immunology

shellers.

University of Texas Medical Branch, Galveston TX

P: 409-747-6865; E: nigarg@utmb.edu



Ben G. Raimer, MD, MA, FAAP President, ad interim

301 University Blvd Galveston Texas 77555-0129 O 409 772 1902 F 409 772 5064

June 16, 2021

Nisha Jain Garg, PhD, MBA Scientific Integrity Officer Professor, Microbiology & Immunology University of Texas Medical Branch, Galveston TX P: 409-747-6865; E: nigarg@utmb.edu

RE: Investigation Determination - Respondent J-H Yoon, PhD

Dear Dr. Garg,

I am in receipt of your letter dated June 16, 2021 in which you asked that I make a determination with regard to whether a research misconduct investigation is warranted in Jung Hoon Yoon's case. I have reviewed your letter as well as the Scientific Integrity Report which is to be treated as an Inquiry Report and agree with the UTMB Scientific Integrity Committee's assertion that an investigation is warranted Please move forward with the investigation phase in this matter.

Furthermore, I hereby appoint UTMB's standing Scientific Integrity Committee as the investigation committee in this matter. The members of the investigation committee shall be as follows:

MEMBERS

B. Montgomery Pettitt, PhD Rebeca Wong, PhD V. Suzanne Klimberg, MD Lorraine Evangelista, PhD Blake Rasmussen, PhD Giulio Taglialatela, PhD David H. Walker, MD

Ex-officio

Ms. Carolee A. King, JD
Ms. Sharon A Comvalius-Goddard

Scientific Integrity Officer and Chair Nisha J Garg, PhD, MBA

Sincerely,

Ben G. Raimer, MD, MA, FAAP

Buc. Rawan

President, ad interim

www.utmb.edu Working together to work wonders. The University of Texas Medical Branch Member, Texas Medical Center



Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D. Phone: 805-444-7865 Fax: 805-322-4469

July 26, 2021

Nisha Jain Garg, Ph.D., MBA Scientific Integrity Officer Professor, Microbiology and Immunology University of Texas Medical Branch, Galveston O: 409-7476865

E: nigarg@utmb.edu

RE: Response to Investigation of Drs. Louise, Satya Prakash and Dr. Jung-Hoon Yoon

Dear Dr. Garg,

I have been engaged by Drs. Louise and Satya Prakash (individually, "Dr. L. Prakash" and "Dr. S. Prakash" and collectively, the "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") to represent them regarding the investigation undertaken by you on behalf of the University of Texas Medical Branch, Galveston ("UTMB") as UTMB's Scientific Integrity Officer ("SIO") regarding the genesis of Supplementary Figure 2 ("Figure S2") that was published in Genes & Development 33:282 – 287 (2019) (the "G & D paper").

I understand that your investigation started based on a complaint filed by a former member of the Prakash lab group who worked with Drs. Prakash. This complaint was filed with you as SIO in May 2019 and claimed that Figure S2 did not include the right gels.

I also understand that upon learning of the mistake regarding Figure S2 on or about September 2019, Dr. Yoon reran the experiments and then took the new gels to create a substitute Figure S2. This substitute Figure S2 was sent to G & D to be published as a Corrigendum. I understand that the substitute Figure S2 was accepted and published as a Corrigendum by G & D. I understand that the inclusion of Figure S2 did not affect the findings and conclusions of the G & D paper. Indeed, it is my understanding that the papers findings and conclusions would have been the same without Figure S2. Thus, Figure S2 was not material.

As stated earlier, it is not contested that Figure S2 was not material to the findings and conclusions of the G & D paper. Thus, one element that is missing regarding a misconduct





claim is intent. Indeed, Dr. L. Prakash and Dr. S. Prakash have about five decades of outstanding published research and are considered leaders in their field. Dr. Yoon has worked for them for about sixteen (16) years, with many highly regarded publications and no issues regarding his credibility or competence. Thus, there is no past pattern of misconduct by any of these three scientists. What these facts suggest is an honest mistake.

At the outset I must state that I am amazed and stupefied at how you as the SIO have handled this matter to date. As will be detailed below, from the very beginning of the process, you have failed to follow the procedures and rules set forth in UTMB's Policy and Procedure Manual on Integrity in Research ("PPMIR"). The PPMIR sets forth in simple language how you, as SIO, were to handle this matter. What makes this more perplexing is that you as SIO are charged with the knowledge of the procedures set forth in the PPMIR. Despite the clear requirement of you as SIO to know the procedures to handle a complaint about alleged misconduct, you failed to follow them not once, but now twice. Based on your failures and those of the Scientific Integrity Committee ("SIC"), Dr. Yoon, Dr. L. Prakash and S. Prakash have suffered greatly and continue to suffer.

Now as stated in their letter to you dated March 3, 2020, that was signed by Dr. L. Prakash. Dr. S. Prakash and Dr. Yoon, the PPMIR lays out specific steps that are to be followed by the SIO in conducting an inquiry that may lead to an investigation. As you are in possession of the March 3, 2020, letter, which I attach hereto as Exhibit A, I will not reiterate what has already been clearly laid out for you. However, I will state that before you were to start an investigation, you were to conduct an inquiry. At the end of the inquiry, you were to prepare a report as detailed very clearly in the PPMIR on page 10. These elements include (i) a summary of the inquiry process used; (ii) a list of the research records reviewed; (iii) the basis for recommending or not recommending that the allegations warrant an investigation; and (iv) any comments on the draft report by the Respondent or Complainant. Then when you created an inquiry report, you were to provide the findings of the inquiry to Drs. Prakash and Dr. Yoon and allow them to provide their written comments on the findings. Then and only then, you could provide the President of UTMB a copy of the inquiry report. But in doing so, you were also to provide to the President of UTMB the comments from Drs. Prakash and Dr. Yoon. As you are well aware, that is not what happened in the Fall of 2019.

The power to launch an investigation is vested solely in the President of UTMB. Only the President has the power to grant the right to start an investigation, *NOT* the SIO. Additionally, only if the President decides that an investigation is warranted can the SIO provide ORI with the President's written decision, as well as a copy of the inquiry report. Instead of following the clearly defined and simply stated PPMIR procedure, you took it upon yourself to launch in your words an "Investigation" of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. This started in September 2019, four months after the original complaint was filed. You then convened an SIC meeting in December 2019 to determine their guilt. Here again you failed to comply with UTMB's rules set forth in the PPMIR, which clearly state that the investigation committee is to





be formed only after the President of UTMB provides his written approval to start the investigation. Regarding the investigation committee, each of the individuals chosen was to be approved by Drs. Prakash and Dr. Yoon to ensure there was no conflict that would result in a prejudiced decision. Instead, you established an SIC without notifying Drs. Prakash and Dr. Yoon. You then compounded your mistake by failing to provide Drs. Prakash and Dr. Yoon an opportunity to review the SIC member list to provide their feedback and ensure there were no conflicts.

In November 2019, prior to the SIC meeting in December 2019, each of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon sent you a letter. (*see*, Exhibits B – D attached hereto). In these letters, you were provided a reasonable explanation how the error which led to the original Figure S2 occurred. Just as important, you were provided in great detail the measures undertaken by Dr. L. Prakash and Dr. Yoon to ensure a similar mistake *could not occur again*. It is clear by what happened next that you either did not read their letters or you ignored them. What is clear is that you never spoke with any of Drs. Prakash or Dr. Yoon about their letters that were sent to you, the SIO. I also reasonably believe that they were never provided to the President of UTMB or the SIC.

So, you continued your Investigation (your word at the time) and held the SIC meeting in December 2019 where a *judgment* was rendered. Dr. Yoon was to be fired. This was summarized in the "INVESTIGATION REPORT" of January 2, 2020, which is attached hereto as Exhibit E. It is clear from your INVESTIGATION REPORT that you did not read the letters from Drs. Prakash and Dr. Yoon. (*see*, Exhibits B – D). If you had, then the SIC would not have stated as a recommendation on page 3 of your INVESTIGATION REPORT – Recommendations of the SIC.

"that the Department Chair "evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis."

As stated, a process to ensure a similar mistake would not occur had already been implemented and was laid out for you *clearly* in the November 13, 2019, letter from Dr. Yoon. (*see*, Exhibit D). The fact that the SIC is not aware of the implementation of this procedure by Drs. Prakash's lab, clearly shows that you as SIO failed to provide them this critical information prior to the December 2019 SIC investigation meeting.

With the verdict from your investigation in hand, you pass on the verdict from your SIC to Drs. Prakash and Dr. Yoon on February 6, 2020. However, as you should know from the PPMIR, it is the President who decides on the appropriate action to be taken and only after the President determines that the findings substantiate the allegation of research misconduct. As is clear, you as SIO and the SIC had no legal basis to render such a verdict. In rendering a final judgment, you and the SIC *violated* the UTMB PPMIR and as a result you and the SIC caused and continue to cause great harm to Drs. Prakash and Dr. Yoon.





Now for reasons I do not understand, after Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon sent you their March 3, 2020, letter (*see*, Exhibit A) that laid out in detail all of your mistakes regarding the process set forth in the UTMB PPMIR and other issues with the verdict, you did not respond. Indeed, Drs. Prakash and Dr. Yoon did not hear from you again for almost a year when you sent an email to Dr. L. Prakash, as well as Valerie Rosemond and Carolee King, both of UTMB on March 23, 2021. (*see*, Exhibit F attached hereto). In your email, you stated that you had been asked by the Office of Research Integrity if the administrative actions, meaning the verdict rendered by the SIC in the INVESTIGATION REPORT, had been implemented. You then required that Dr. L. Prakash respond to you by March 29, 2021, with the answer.

On March 25, 2021, Drs. L. and S. Prakash responded. (*see*, Exhibit G). They pointed out to you that it was "perplexing" that you had ignored their March 3, 2020, letter, where you were informed in great detail that you *failed* to follow the UTMB PPMIR and *violated* their rights. If you, the SIO, had paid attention to their March 3, 2020, letter, at minimum, you ought to have realized right then that you and the SIC had made a grave error in having informed ORI. It was incumbent upon you at that time to have informed ORI that you had failed to follow the *required* steps of an inquiry under the UTMB PPMIR. You should have informed the ORI that you and the SIC failed to handle this matter properly. Then, you should have withdrawn the report from ORI and apologized to the ORI for your serious mistake. Of course, you and the SIC failed to undertake any of these required steps. As a result, the entire tainted process you pursued and the submission of the report to ORI were illegal, unwarranted, reckless, and extremely damaging to Dr. Yoon and Drs. Prakash.

As you should be well aware, your standard regarding how Dr. Yoon is to be treated for a single honest mistake must be applied to you as SIO and the SIC. Indeed, I would expect that you would agree that you as SIO should not receive preferential or better treatment than Dr. Yoon. Particularly, where you as SIO are charged with knowing the procedures and rules to be followed pursuant to the UTMB PPMIR. Indeed, your failure should be considered worse than Dr. Yoon's honest mistake. As under your own rules there are no do overs, I will continue to call the inquisition you launched and continue to prosecute an Investigation. I will also continue to call the January 2, 2020, verdict, the INVESTIGATION REPORT.

However, I do agree with that part of your statement that the SIC did not find any research misconduct by Dr. L. Prakash or Sr. S. Prakash. I also believe that based on this correct finding, that it was right to close the case against Drs. Prakash. I also understand that the NIH Office of Research Integrity ("ORI") came to the same conclusion in a letter sent to you on June 21, 2021, from Alexander Runko, Director, Division of Investigative Oversight, ORI. (see, Exhibit H attached hereto).

Response to SIO Investigation 7/26/2021



Next, I understand that you sent the INVESTIGATION REPORT to President Ben G. Raimer to request permission to start an investigation into Dr. Yoon. In doing this, you once again failed to allow Dr. Yoon to provide comments for President Raimer to assist in his decision. You also failed to interview Dr. Yoon or Drs. Prakash. So now for a second time, you failed to follow the procedures and rules set forth in the UTMB PPMIR. As you should be able to imagine, this is amazing and perplexing all in one. You were informed of your violation of UTMB's PPMIR almost a year and a half ago. You acknowledge in your discussions with the Director of ORI (your June 3, 2021, letter to the respondents) that you had made a mistake in labeling the SIC Report as an Investigation Report. It can only be assumed that this was based on the information provided by Drs. Prakash and Dr. Yoon. So, the SIO who wants Dr. Yoon fired for a single honest mistake continues to make mistake after mistake, even after being informed of her mistakes.

However, you received the result you wanted. You were able to intentionally mislead President Raimer and obtain his approval of an investigation into Dr. Yoon by gaming the system. You failed to inform President Raimer of your repeated failures to follow the rules as set forth in the UTMB PPMIR. The irony is that your compounded failures fail the standard of what one would hope for regarding a Scientific Integrity Officer of UTMB who is charged with upholding the school's standard of "Integrity."

With President Raimer's improperly attained approval in hand, you next requested that Dr. L. Prakash send you a list of Dr. Yoon's publications over the last five (5) years, which she did. And now, you are continuing your fishing expedition by asking for Drs. Prakash to send you the last five (5) years of their grant applications. To this, I say no on behalf of Drs. Prakash and Dr. Yoon. This inquisition needs to end and if there is an accounting to be had, it is of your incompetent and malevolent conduct and behavior as SIO in this affair. Indeed, it raises the serious question whether the SIO should be the one who is fired.

As stated previously, as SIO you are to follow very specific and simple rules and procedures on how to conduct an inquiry. Then, if reasonable and necessary, and following President Raimer's approval, you can conduct an investigation following the procedures set forth in UTMB's PMIR. You failed in this simple task, not once, but again after having your first failure pointed out to you. You continue to prosecute your inquisition, while failing to follow your own rules.

Further, throughout your inquisition, you have failed to provide an answer to a key component of the inquiry. Why would Dr. Yoon have intentionally created a false Figure S2 if it was not material. Particularly, when he has no history of falsifying data. You never obtained this answer because you never interviewed him on this specific point. If you had, you would have learned it was an honest mistake due to the pressure of working on multiple things at once on his computer as he stated in his November 13, 2019, letter to you. (*see*, Exhibit D). I would doubt that you or someone working in your lab has not or could not have made a similar mistake under the same circumstances.

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Thus, based on the facts in this matter, it is clear that if there is to be an investigation, it should be of you and your conduct as SIO. You have tortured Drs. Prakash and particularly, Dr. Yoon for almost two (2) years with your inquisition for a simple non-material and honest mistake. You have caused each of them great physical, emotional and mental harm and whether you realize it, professional harm. You have done this despite Dr. Yoon letting you know of the great emotional, mental and physical toll your inquisition has taken on him personally. It is clear you do not care for their wellbeing.

Now your behavior and conduct as SIO raises serious legal and administrative issues. This includes your violation of Regents Rules of Conduct, Rule 30103. This rule explicitly states that any employee who, acting singly or in concert with others, obstructs, disrupts, or interferes with any research or other activity authorized to be held or conducted on campus or on property or in a building or facility owned or controlled by The University of Texas System or any of the institutions is subject to disciplinary action, including dismissal. It goes without saying that your willful inquisition, which has not followed the explicit rules and procedures set forth in the UTMB PPMIR has clearly disrupted the research and other activities of Dr. L. Prakash, Dr. S. Prakash, and particularly, Dr. Yoon.

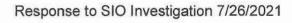
But your violations of the Regents Rules of Conduct do not stop there. Rule 30602 states that

"it is the policy of the University of Texas system or any of the institutions to encourage, fair, efficient, and equitable solutions for problems arising out of the employment relationship and to meet the requirements of State and Federal law."

It goes without saying that the inquisition that you have pursued against Drs. Prakash and Dr. Yoon has not been fair, efficient or resulted in an equitable solution. Instead, it has been wholly unfair, unreasonable, inefficient and just cruel. Particularly, when you consider the improper and illegal judgment of you as SIO and the SIC in the INVESTIGATION REPORT that Dr. Yoon be fired after 16 years of outstanding service for a non-material and honest mistake. In what universe can this be reasonably considered as an equitable solution. Your inquisition has caused Dr. Yoon great mental and physical anguish. It has resulted in serious emotional trauma.

Thus, it goes without saying that your actions over the last two (2) years as SIO of UTMB have resulted in cognizable and significant damage to each of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. So here is what we expect to happen to close this matter. You will provide a letter to Dr. Yoon stating that there is "no evidence" of misconduct by him. This will be shared with President Raimer, the ORI and each member of the SIC. Then you will close this matter.

Failure to take this reasonable step and end this charade will require Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon to consider the legal and administrative remedies available to them. As I am sure you are aware, these include obtaining legal redress for the cognizable harm they have suffered from the actions you as an individual have taken against them personally (clear federal civil rights violations), UTMB and the members of the SIC. It will also include filing a complaint





against you personally as SIO of UTMB with the General Counsel's Office of the University of Texas system for your actions and continued and knowing violation of the Regents Rules of Conduct and UTMB's PPMIR to the significant detriment of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. Other administrative remedies will also be considered.

This whole inquisition should have been terminated following your receipt of the letters from Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon in November 2019. By then the non-material and honest mistake had been corrected and procedures had already been implemented to ensure it would not happen again. But you decided to press your inquisition to the significant detriment of everyone, including UTMB and President Raimer. I expect that this will end now.

Sincerely,

Peter D. Weinstein, Ph.D., J.D.

Managing Partner

Response to SIO Investigation 7/26/2021



EXHIBIT A



6.104 Medical Research Building 301 University Boulevard Galveston, TX 77555-1061 O 409.747.8601

March 3, 2020

Dear Dr. Garg:

This letter is in response to the Investigation Reports you sent to each of us, the Respondents, Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.-H. Y) on Feb. 6, 2020 at 4:14 PM, in which you reproduce the allegations made by the complainant of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our Genes & Development publication, vol. 33, 282-287, 2019. These letters list the members of the UTMB standing SIC involved in both the Inquiry and Investigation and the Summary Statement and Recommendations of the SIC. Given serious issues with the process and significant concerns about the content of this investigation, we object to the recommendations proposed in it, namely dismissal of Dr. Jung-Hoon Yoon from UTMB.

Let me start with our serious concerns about the process. The guidelines of the Policy and Procedure Manual on Integrity in Research (PPMIR) are very clear on the steps that need to be taken in determining the merit of allegations of misconduct; however, as documented below, the proper procedures were not adhered to in this particular case.

Since the guidelines indicate that an inquiry report, which we have not seen and suspect does not exist, should have been sent to the President, we have copied him on this communication; and since we have discussed this matter with the Chair of our Department, we have copied Dr. Mariano Garcia-Blanco as well.

Page 7, section IV E of the PPMIR, states: "During the research misconduct proceeding, the SIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for by law and UTMB policies and procedures."

We did not receive any notices during the proceedings

We list below specific examples where proper procedures were not followed, along with our comments noted in bold:

- (1) Section VI A p.10 of the PPMIR details what the written Inquiry report should contain. Among other items, it should include a summary of the inquiry process used, a list of the research records reviewed, the basis of concluding whether or not an investigation is warranted, and any comments on the draft report by the Respondent or Complainant.
 - We were not provided with any such information and were given no opportunity to comment on the inquiry report.
- (2) Section VI B on p. 10 of the PPMIR states that the SIO shall provide a copy of the inquiry report to the President and to the respondent at the same time and that the respondent has 10 calendar days to send comments to the President regarding the contents of the inquiry report.
 - We were never given a copy of the inquiry report; therefore, we were not allowed the opportunity to send our comments to the President.

- (3) On p. 11 in section VI B of the PPMIR, it states that "The President will determine in writing whether an investigation is warranted."
 - The letters we received from you on Feb. 6, 2020 were entitled "INVESTIGATION REPORT" and state that the SIC members determined there was sufficient ground to proceed to the investigation step. This implies that several steps in the mandated process were not carried out according to the guidelines set forth in PPMIR.
- (4) Once the President has determined that an investigation is warranted, in section VII C, p. 12 of the PPMIR, it states that "The President, in consultation with the SIO and other institutional officials as appropriate, will appoint an investigation committee of at least 3 members..." Thus, the SIC and the Investigation Committee are NOT the same.
 - The bottom of page 1 of the letters we received from you lists the names, etc. of the UTMB SIC members involved in BOTH the inquiry AND the investigation.
- (5) On p. 12, in section VII C of the PPMIR, it states that "The President will notify the Respondent of the proposed committee membership to give the Respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest."
 - We never received any such notification. In fact, as noted above, the SIC committee performed both the inquiry and investigation reports whereas in the email of Sept. 17, 2019 at 1:25 PM, we were notified that it was an inquiry which you would like to complete in 60 days.
- (6) According to p. 13, section VII E of the PPMIR, the investigation committee and the SIO must interview each Respondent and Complainant.
 - None of us, the respondents, were interviewed by the Investigation Committee.
- (7) Section VIII. A on p. 14 provides a list of the elements that the written draft of the investigation report needs to include.
 - No details were provided in the investigation report.

The SIC's actions are even more troublesome in view of the fact that we had provided all the information we were asked for, as noted below.

Your email of Sept. 17, 2019 at 1:25 PM stated that "We would like to complete the inquiry in the next 60 days". In a later email that day (Sept. 17, 2019 at 3:28 PM) you wrote "Please provide us, in defense, documentation for the ability to detect endogenous level of Rev1, DNA Polymerase lota, DNA polymerase kappa in human or other cells used in the study, and original Western blots / images of the original blots, and documentation of the experiments." We, all 3 respondents: Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.H.-Y) provided you with extensive documentation of our ability to carry out these studies in our November 18, 2019 response to you. In addition, we provided the corrigendum for Supplemental Fig. 2 that has been published in Genes & Development. And in our letters (SP & LP), we pointed out the highly error-free track record of Dr. Yoon and we noted that the inclusion of Supplemental Fig. 2 had no bearing on the impact or conclusions of this study.

Between Sept 17 and Nov 18, before we sent you our letters of response, I (LP) communicated with you by telephone several times for advice on what information to include in our response. After

spending many hours examining the complainant's notebooks and comparing relevant pages to the Western Blots (WBs) he referenced, I found many discrepancies which led me to question the validity of his allegations. In the draft of my original response, I had included the following statement: "I want to point out that I spent a lot of time examining the notebooks of the individual making the complaint and I found several instances in which the points brought out by the complainant did not confirm the allegation." We (SP & I) accepted your suggestion to remove this statement because we were given the impression that it was not necessary - thinking that all you needed was the evidence you had asked for in your Sept. 17, 3:28 PM email. Therefore, we were shocked and traumatized to receive your email of February 6 with the attached Investigation Report letters, since we had not been made aware that the Inquiry Phase had progressed to the Investigation Phase.

We (LP & SP) have discussed this situation with our Chair, and respectfully request that the Guidelines of the PPMIR be followed and that the Inquiry and subsequent steps be re-initiated from the beginning. Importantly, I (LP) have uncovered that the majority of the complainant's allegations cannot be substantiated, and it is only if the Inquiry is followed in the proper order that we can discuss these issues with the SIC inquiry committee, and with the Investigation Committee, should it proceed to that stage.

The precipitous action of the SIC and its recommendations, especially the extreme one that Dr. Yoon be terminated from UTMB, without consideration of his excellent track record, path breaking publications, and his devotion to science (for a detailed explanation see our letters that were included in our Nov. 18, 2019 email to you and are attached here) have been extremely devastating to all the respondents. We also feel that no consideration was given to the circumstances under which this error occurred, for which Dr. Yoon has been extremely remorseful, and the steps we have undertaken to avoid such errors in the future (see Section §93.408 Mitigating and aggravating factors in HHS administrative actions, p. 648 of Public Health Service: Policy on Scientific misconduct 42 CFR Part 93).

Content of Allegations

In this communication, we have not addressed in detail the content of the allegations. We will comment on them at the appropriate stage and will do so in great detail.

Thank you very much.

Sincerely.

Louise Prahash
Louise Prakash
Satya Prakash
Satya Prakash
Jung-Hoon Yoon



Response to SIO Investigation 7/26/2021

EXHIBIT B



Subject: Genes & Development paper

November 5, 2019

Dear Committee:

At the outset, I categorically state that I had no knowledge of any issues with the western blots (WBs) shown in Supplemental Figure 2 and I was in no way involved in any of the aspects of constructing this figure.

I have worked closely with Hoon since he joined our group in March 2005. In my long academic career, he is one of the very best colleagues that I have worked with. Hoon has high ethical standards; he cares deeply about discovering the truth and reporting the scientific facts, and his impeccable and impressive first author contributions with us over the past 10 years attest to this fact.

I have thought long and hard about how Hoon, who is such a diligent and highly conscientious individual who repeats experiments too many times to assure the accuracy of his data and conclusions, could end up being responsible for mixing up the information assembled in Supplemental Figure 2. Knowing Hoon as a person and as a scientist as well as I do, knowing the difficult circumstances in which this work was being put together, and the fact that he shares all the important aspects of a project with me, regardless of how negatively that may impact the outcome of the study or its publication, and irrespective of the time he has spent on it, I can affirmatively say that there is absolutely no way that this highly distressing episode occurred because it was in any way intentional.

In the original version of the paper submitted to G&D, we had not included Supplemental Figure 2 because the observation that depletions of respective DNA Pols reduce the frequency of translesion synthesis (TLS) opposite1,N6-ethenodeoxyadenosine (ϵ dA) had provided strong genetic evidence for the effectiveness of siRNA depletions and also because we had published such evidence before. Moreover, since in the revised version, we had included the evidence generated in Rev1- $^{1/2}$ and Pol $^{1/2}$ mouse embryonic fibroblasts (MEFs) that a reviewer had asked for, it was not necessary to include a western blot (WB) figure of siRNA depletions,. Even then I decided to include a WB figure of siRNA depletions in the revised version and asked Hoon for such a figure. I believe that this unnecessary and undue burden I put upon Hoon to assemble such a figure in a short time led to errors in compilation of this figure.

Over the years, Hoon has been working almost single-handedly on a number of novel and path-breaking projects and he has been under pressures which he puts upon himself and the pressures that I put upon him. I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion. Clearly, he did not realize the degree of mental exhaustion or the mistakes he was making when he put the figure together. It is impossible for me to see that Hoon, who cares so deeply about the validity of his results and conclusions, would knowingly misrepresent a figure which has little bearing, if any, on the data shown in the paper or on the conclusions drawn. A person with intent to falsify or misrepresent data would do so for aspects which elevate the impact of the study and not something as marginal as this figure.

In reviewing all the past contributions of Hoon with us, I have become deeply aware of the immense amount of information he puts together in preparation for each paper, and of how error-free and meticulous each of his publications is. Nevertheless, to avoid the possibility of any errors in the future, I will help Hoon in verifying the accuracy of each of the items that are included in the paper. I will also make sure that Hoon is not working on a number of different projects at the same time.

Hoon has been traumatized by the fact that he is responsible for this mishap in the figure. He is a highly devoted scientist who cares deeply about the accuracy and biological relevance of his findings and over the years with us, he has been responsible for a number of pioneering studies published in a number of leading journals, including Cell, Genes & Development, PNAS, and others Moreover, Hoon has been working assiduously on a number of other important projects. I strongly believe that publication of these studies will be highly impactful and paradigm shifting for a number of DNA repair genes which play highly effective roles in protection from breast and ovarian cancers and from leukemias.

Sincerely yours,

Satya Prakash, Ph.D.

Satya Pracash

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology 6.104B Medical Research Building

Telephone: 409-747-8602 e-mail: saprakas@utmb.edu

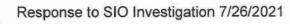




EXHIBIT C



Subject: Genes & Development paper

November 13, 2019

Dear Committee,

I wish to state at the outset that I was not involved in any way in assembling the data for the gels presented in Supplementary Figure 2. My role was to combine the Supplementary Figure files given to me into one pdf file for submission to the journal, along with the text and text figures.

Both Satya and I were shocked when we learned about the allegation against Dr. Jung-Hoon Yoon, the first author of a manuscript published in Genes & Development in March of this year. It is important to understand the kind of person that Hoon is because then it becomes totally incomprehensible that Hoon could have knowingly and intentionally misrepresented the data in Supplementary Figure 2. He has been with us for the past 14 years, and during that time, I have had ample opportunity to observe the way he conducts himself in his research and how meticulous he is with his data. He is extremely honest, forthright, conscientious, and a most trustworthy, reliable, hardworking, and responsible individual. He always repeats his experiments numerous times to be as sure as one can ever be in science that the data are reproducible and that the conclusions are warranted. The quality and quantity of work that has gone into each of his publications shows that he has accomplished a phenomenal amount of work. He has single-handedly been doing the work that in other labs would be handled by a number of individuals. In fact, one of the reviewers of the recent Cell paper on which Hoon is first author said "This is a monumental work that addresses a key problem in skin cancer and elucidates the roles of Polθ and other TLS polymerases." (Underline mine). And another reviewer wrote "These data provide unambiguous evidence of skin cancer arising in the absence of UV induced mutations. This is a paradigm-shifting finding as it questions the dogma that UV induced mutations cause skin cancer". In this paper as well as in all his other papers, Hoon has been the prime mover - being responsible for the major aspects of the study.

After going over the details with Hoon it has become clear to me that Hoon was working under tremendous pressure at the time he prepared this figure. He was asked by Satya to provide a figure of western blots showing siRNA knockdowns of the various TLS polymerases used in the study, Hoon made errors because during compilation of a number of western blots, he had many gel images open at the same time, and he picked the wrong images. When Hoon realized what he had done, he was completely devastated. He blamed himself endlessly, and felt strongly that he has brought shame on himself as well as on all others associated with him. It took several days for him to recover sufficiently to be able to address with us the details of how this might have come about. He made a genuine mistake, and I cannot over-emphasize how truly remorseful he has been. This is all because he takes his scientific work very seriously.

I have gone over various ways to reduce the probability of errors arising in the future regarding confusion in identifying western blots or similar types of data. We both agree that annotating each blot with a western blot marker pen such that the date and samples are clearly indicated will be most useful to achieve this end. In addition, applying the same code to the original file

name created by the ImageQuant instrument and to the corresponding blot should avoid any ambiguity as to the identity of the blot. He will also keep a detailed record in a lab notebook where the code name will include an illustrator file of the blot and a legend indicating what is in each lane and the relevant experimental conditions used. From now on, I will carefully go over with Hoon's record keeping in this regard and I am confident that this strategy will serve to avoid mistakes in the future.

We have compiled a new Supplementary Figure 2 and have sent this figure to Genes & Development to be published as a Corrigendum. I have been corresponding with Dr. Laureen Connell, Senior Editor, Genes & Development, regarding the corrigendum and there do not seem to be any issues with replacing the figure. The emails from Dr. Connell are included with the materials provided to the committee.

Thank you for giving us the opportunity to explain the circumstances that led to mistakes in the compilation.

Sincerely yours,

Louise Prakash, Ph.D.

Louise Prakash

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology 6.104A Medical Research Building

Telephone: 409-747-8601

e-mail: loprakas@utmb.edu





EXHIBIT D



November 13, 2019

Letter of Explanations to Scientific Integrity Committee

In going over Supplementary Figure S2, I have realized that I failed to keep a record of how I had compiled this figure and it has become clear to me that I made errors in assembling this figure. I am always very concerned about the accuracy and repeatability of my data and I have been extremely upset about not being careful in assembling this figure I want to emphasize that all these mistakes are unintentional errors and I wish to explain the circumstances under which this figure was made.

I joined the Prakash lab in 2005 with a specific purpose of studying translesion synthesis (TLS) mechanisms in human cells. For this purpose, I designed a novel duplex plasmid system in which replication through a site-specific DNA lesion present on the leading or the lagging DNA strand could be analyzed methodically. For determining the contribution of various TLS polymerases (Pols), I began using siRNA depletion method as this approach avoids the complications of genetic suppression or other genetic artifacts that accompany null mutations. After over two years of effort, I established the plasmid system and optimized the efficient siRNA depletion conditions for a number of TLS Pols in human and mouse cell lines. To confirm the efficient siRNA depletion of TLS Pols in mammalian cells, I used western blot analysis and if necessary, RT-PCR. The establishment of these approaches has allowed me to systematically analyze the genetic control of TLS opposite different types of DNA lesions in human cells and these studies have been published in prestigious scientific journals.

When I prepared the Figure S2 for the Genes & Development paper, I was working under tremendous pressure of time and of having to deal with a number of different ongoing studies. Moreover, in the last year I had taken over the work of post-docs who had left the laboratory. At the same time, I was handling a rather complex paper for Cell, and when Satya wanted me to provide a new figure for siRNA depletions, because of the concern for the revision deadline, I rushed to finish the figure. I opened many files of western blot images on the computer screen and because of lack of attention and confusion, I mixed up the files and didn't double check the final figure before submission. I do realize that there is no excuse for my making these mistakes; from now on, I will be much more careful so that such mistakes never happen again.

To avoid such errors from occurring in the future, I have discussed a strategy with Louise which I plan to follow. Our laboratory uses the ImageQuant LAS4000 camera system for obtaining digital images of our western blots of other samples. The digital images are produced by exposing the blot to chemiluminescence and the system automatically names the file with the date it is created. From now on, for each file genrated by the ImageQuant, I will add a code name to each corresponding blot using a western blot marker pen so that there will be no ambiguity as to the identity of the samples in a particular blot. In addition to annotating each blot with the date and sample name, I will keep a detailed record of each blot in a notebook where every lane of the particular blot will be clearly labeled as to what sample is in each lane, what antibody was used, and any other pertinent experimental details. Blots will not be copied into adobe illustrator until they have been clearly marked. We expect that this procedure will substantially reduce the probability of error. In addition, I will consult with Louise and show her my annotation system so that there will be no confusion as to what each blot represents.

Thank you very much for considering my explanation of the circumstances that led to this unfortunate, and entirely unintentional, incident for which I take full responsibility.

Sincerely yours,

Jung-Hoon Yoon, PhD Research Scientist

Biochemistry and Molecular Biology

6.108 Medical Research Building

Telephone: 409-747-8604; e-mail: juyoon@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT E

University of Texas, Medical Branch in Galveston ("UTMB")

Confidential Sensitive

Allegations of Research Misconduct Respondent: Prakash Satya, PhD

Date of SIC Meeting: December 19, 2019

Report Date: January 2, 2020

1. INVESTIGATION REPORT

1.a. Background and summary of Inquiry

In a message dated May 5, 2019, allegations of research misconduct were raised by a complainant. The allegations stated possible research misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019).

Panel A - top left: blot for TLS Pol in NC/Poln samples is from another blot for a different protein.

Panel A - middle left: Polo data is from another blot for a different protein in different cells, Rev1 blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Polt data are from a blot for another protein.

Panel B- Western blot for Poli and tubulin for NC/Polo samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data This manuscript cites support from US PHS funds, specifically NIH grants ES022948 and GM126087 (PI: Prakash).

Though the complainant identified Yoon, Jung-Hoon, PhD, Research Scientist in the Department of Biochemistry and Molecular Biology (BMB) as respondent. Dr. Yoon was identified to directly report to Dr. S Prakash. Thus, Dr. S Prakash was also identified as respondent.

Dr. NJ Garg Scientific Integrity Officer (UTMB) met the complainant in May 2019 and received the material justifying the allegation. The material received from complainant is attached as **Appendix 1**.

Dr. Garg (and Ms. Bricker) met Dr. Yoon, Dr. S. Prakash and Dr. L Prakash (identified as respondents) on Sept 16 and Sept 17 to present the allegation. Notebooks and computer hard drive were sequestered on September 16. The Scientific Integrity Committee members determined there is sufficient ground to perform investigation.

The Investigation

1.b. Names, titles and CVs for UTMB SIC members involved in Inquiry and Investigation.

The members of the UTMB standing SIC are listed below. The biosketches of the members are available on request.

Dr. Nisha J Garg, PhD MBA (Professor, Microbiology & Immunology, School of Medicine (SOM) and Scientific Integrity Officer)

Confidential/Sensitive

Dr. Giulio Tagliatela, PhD (Professor, Neuroscience, SOM and Chair, SIC)

Dr. David H Walker, PhD (Professor, Pathology, SOM)

Dr. Lorraine Evangelista, PhD (Professor, School of Nursing)

Dr. Blake Rasmussen, PhD (Professor, Nutrition and metabolism, School of Health Professions)

Dr. Rebeca Wong, PhD (Professor, Preventive Medicine and Community Health, SOM)

Dr. B Monte Pettitt (Professor, Biochemistry & Molecular Biology, SOM)

Dr. V Suzanne Klimberg (Professor, Surgery, SOM)

Ms. Carolee A King (JD Senior Vice President & General Counsel, ex officio member)

Ms. Kimblyn Raschke / Ms. Nancy Bricker (Administrative support, ex officio)

1.c. Names and titles of all respondents:

Respondent S Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent L Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent Yoon, Research Scientist, Biochemistry and Molecular Biology, UTMB

1.d. Attorneys if relevant: None

1.e. PHS support/ORI jurisdiction.

The following grants funded by NIH were cited in the publication:

Paper Grants

Paper: Genes & Development 33:282-287 (2019) ES022948 and GM126087

2. Investigation process:

Dr. Garg and Ms. Bricker met the respondents on Sept 6-7, 2019 to present the allegation and sequester the relevant notebooks and hard drive.

The respondent L Prakash kept contact with Dr. Garg through emails and phone calls and provided detailed response on November 18, 2019. The statements received from all respondents are attached as **Appendix 2**. Respondent has also provided new data (**Appendix 3**) and communications with the journal (**Appendix 4**).

The collected information and data were sent to the members of the SIC investigation committee electronically on 11/19/2019. Members discussed the case electronically and formally met on December 19, 2019.

The presented report was approved by SIC members by January 25, 2020 and the legal counsel on February 6, 2020.

3. Summary:

Dr. S Prakash (respondent) states, "I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion". Dr. S Prakash (respondent) maintains that it was an honest error of Dr. Yoon.

All respondents could not identify the original gels that were used to submit Figure S2. Lacking that, all experiments/WB for Figure S2 were repeated, and new data were utilized to assemble new Figure S2 (attached as Appendix 3). The newly generated Figure S2 was sent to the G&D journal (Appendix 4). The journal accepted to publish revised version of the Figure S2 as corrigendum.

Scientific Integrity Committee: The person who ran Western blots in the lab has moved to another location. His folders were sequestered and found to be appropriately labeled with all details and needed information. However, the data presented in S2 Figure were found to be cut from images that belonged to data collected with other antibodies. Dr. Yoon was directly involved in assembling the data for publication and he accepted the responsibility for mis-presentation of data. Dr. S Prakash was not identified to have direct knowledge of mis-presentation of data.

SIC members unanimously concluded that falsification and fabrication of data occurred. SIC members considered that a lack of supervision and over-confidence in the capabilities of Dr. Yoon likely resulted in mis-presentation of data. However, SIC members concurred that there is no evidence that suggest that Dr. Prakash had direct knowledge of mis-presentation of data and he was likely not involved in falsification and fabrication of the data presented in Figure S2.

- 4. Recommendations of the SIC: Members of the SIC recommended the following:
 - 1. SIC members request the Chair of the Department to evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis. It will be essential that PI is aware of and has confirmed the accuracy of all raw data to be used for future publications.
 - 2. Notification to the Office of Research Integrity and Federal Funding Agency.
- 5. Notice to the respondent of the institutional decision and administrative action. Pending

Submitted by:

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston

O: 409-747-6865, E: nigarg@utmb.edu

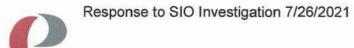


EXHIBIT F

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 181 of 514

From: Garg, Nisha <nigarg@utmb.edu> Sent: Tuesday, March 23, 2021 4:26 PM

To: Prakash, Louise <loprakas@UTMB.EDU>; Prakash, Satya <saprakas@UTMB.EDU>

Cc: Rosemond, Valerie S. <vsrosemo@UTMB.EDU>; King, Carolee A. (Legal) <caaking@UTMB.EDU>

Subject: G&D paper

Hello Louise and Satya. I have been asked by the office of research integrity to address if the administrative actions recommended in Scientific Integrity Committee report are implemented. For this purpose, I request you to let me know the current employment status of Dr. Hoon and the lab procedures/protocols that are implemented/followed to ensure proper recording of the data and gel images in the lab.

Please send your response by Monday March 29th at the latest. Thank you

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer Professor, Microbiology & Immunology University of TX Medical Branch at Galveston O: 409-747-6865; E: nigarg@utmb.edu

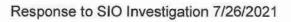




EXHIBIT G

Prakash, Louise

From:

Prakash, Louise

Sent:

Thursday, March 25, 2021 2:27 PM

To:

Garg, Nisha

Cc:

Raimer, Ben G.; Garcia-Blanco, Mariano A.; Rosemond, Valerie S.; King, Carolee A. (Legal)

Subject:

RE: G&D paper

Attachments:

Response to Investigation Report letters

Importance:

High

Dear Nisha,

We find your communication of March 23, 2021 (4:26 PM) perplexing because we had sent you an email letter over one year ago, on March 3, 2020, documenting in great detail our serious concerns regarding the allegation of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our *Genes & Development* publication (2019, vol. 33, 282-287). In addition to sending that email and the attached materials to you, we had copied President Ben Raimer and our Chair, Dr. Mariano Garcia-Blanco. As you will note in that email (which is attached here), we expressed our concerns in detail and cited numerous examples of how procedures described in the <u>Policy and Procedure Manual on Integrity in Research (PPMIR)</u> of the University of Texas Medical Branch at Galveston had not been followed. Since we did not hear from you, we assumed that the matter had been closed. We have discussed this matter again with Dr. Garcia-Blanco and he shares our concerns.

Dr. Yoon's employment status at UTMB remains the same and he continues to make seminal contributions to translesion DNA synthesis mechanisms. Also, we stress that for each experiment we have been following very methodical and stringent procedures to ensure proper recording of the data and gel images.

Sincerely,

Louise Prakash, Ph.D.

Professor, Department of Biochemistry and Molecular Biology
I.H. Kempner Professor in Human Genetics

loprakas@utmb.edu

Satya Prakash, PhD.
Professor, Department of Biochemistry and Molecular Biology
Charles Marc Pomerat Professor in Biological Sciences
saprakas@utmb.edu





EXHIBIT H

DEPARTMENT OF HEALTH & HUMAN SERVICES



Office of the Assistant Secretary for Health Office of Research Integrity 1101 Wootton Parkway, Suite 240 Rockville, MD, 20852

> Phone 240-453-8800 FAX 301-594-0043

Email: alexander runko whhs gov Web: https://ori.dhhs.gov/

CONFIDENTIAL/SENSITIVE

June 21, 2021

Nisha Jain Garg, Ph.D., MBA Scientific Integrity Officer Professor, Microbiology & Immunology University of Texas Medical Branch 301 University Blvd. Galveston, TX 77555-0342

TRANSMITTED VIA EMAIL TO: nigarg@utmb.edu

RE: ORI 2021-18 (DIO 7323)

Dear Dr. Garg:

The Division of Investigative Oversight (DIO), Office of Research Integrity (ORI), has reviewed the report of the inquiry conducted by the University of Texas Medical Branch in Galveston (UTMB) into allegations of possible research misconduct against Louise Prakash, Ph.D., Professor, Department of Biochemistry and Molecular Biology, UTMB. Dr. Prakash allegedly falsified and/or fabricated data in a supplementary figure in one (1) published paper. The questioned paper cited support from U.S. Public Health Service (PHS) funds, specifically National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES022948 and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM126087.

DIO concurs with UTMB's determination that there is insufficient evidence against Dr. Louise Prakash to warrant proceeding to an investigation. Therefore, DIO has administratively closed this case without further action.

Consistent with Federal law and ORI policy, research misconduct proceedings that result in no PHS finding of misconduct remain confidential for ORI. We ask that you respect this policy. We appreciate your reporting to DIO under 42 C.F.R. § 93.309.

¹Yoon J-H, Johnson RE, Prakash L, Prakash S. DNA polymerase θ accomplishes translesion synthesis opposite 1,N°-ethenodeoxyadenosine with a remarkably high fidelity in human cells. *Genes Dev.* 2019 Mar 1;33(5-6):282-87.

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ORI 2021-18 (DIO 7323)

Page 2

If you have any questions about this matter, please contact me at alexander.runko@hhs.gov or 240-453-8800.

Sincerely,

Alexander P.

Digitally signed by Alexander P.

Runko -S

Runko -S

Date: 2021.06.22 16:34:42 -04'00'

Alexander Runko, Ph.D.

Director

Division of Investigative Oversight Office of Research Integrity





The University of Texas Medical Branch SCHOOL OF MEDICINE

September 2, 2021

Peter Weinstein Entralta P.C., a Litigation, Intellectual Property and Business Law Firm 4500 Williams Drive, Suite 212, PMB 511 Georgetown, TX 78633 P: 805-444-7865, E: peter.weinstein@entralta.com

Dear Mr. Weinstein,

We are in receipt of your letter dated July 26, 2021 (the "Letter"). As a recipient of Public Health Service ("PHS") funds under 42 CFR Parts 50 and 93, The University of Texas Medical Branch at Galveston ("UTMB") has an "affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and has primary responsibility for responding to and reporting allegations of research misconduct". UTMB has been in communication with the Office of Research Integrity ("ORI"), which oversees scientific integrity on behalf of the Secretary of Health and Human Services, and has been advised by ORI's Division of Investigative Oversight ("DIO") to proceed with the investigation into Dr. Yoon by treating the mislabeled "Investigation Report" dated January 2, 2020 as an "Inquiry Report" and disregarding the recommendations contained therein as premature. Your client, Dr. Jung-Hoon Yoon was made aware of these details in a letter dated June 3, 2021. As a result, at this time, the inquiry phase has been completed. On or about June 28, 2021, Dr. Yoon received a copy of a letter dated June 16, 2021, notifying him of UTMB President, ad interim Ben G. Raimer, M.D.'s decision to authorize the investigation and appoint an investigation committee. The investigation committee has made no findings regarding whether or not research misconduct occurred, nor has it made recommendations for institutional actions. As part of the investigation, all three of your clients, Dr. Yoon, Dr. Louise Prakash, and Dr. Satya Prakash will be interviewed and have an opportunity to provide exculpatory evidence.

Currently, UTMB requests the last five years of Dr. Louise and Satya Prakash's lab notebooks and copies of unfunded grant proposals that Dr. Yoon contributed to. This request is a result of a DIO recommendation that UTMB review additional papers, presentations, and grants to which Dr. Yoon may have contributed. In your Letter, you intimated that your clients would not be participating in requests for such information. Please note that cooperation with the conduct of investigations is a requirement of UTMB's Policy and Procedure Manual on Integrity in Research, which states, "Institutional members will cooperate with the [Scientific Integrity Officer] and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the SIO or other institutional officials." Failure or refusal to cooperate with an official UTMB process could affect Dr. Yoon's employment status and Dr. Louise and Satya Prakash's memorandums of appointment. Furthermore, such failure or refusal will require reporting to ORI and the National Institutes of Health, the funding agency of the grants, for additional action.

Sincerely,

Nisha Jain Garg PhD MBA Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston TX

P: 409-747-6865; E: nigarg@utmb.edu

¹ Section 93.100 of 42 CFR Parts 50 and 93

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Satya Prakash, PhD, Professor, Biochemistry and Molecular Biology, UTMB Galveston Louise Prakash, PhD, Professor, Biochemistry and Molecular Biology, UTMB Galveston Jung-Hoon Yoon, PhD, Biochemistry and Molecular Biology, UTMB Galveston Carolee A. King, JD, Senior Vice President & General Counsel, UTMB Galveston

From: Peter Weinstein

To: cabremon@utmb.edu

 Cc:
 Peter Weinstein; caaking@utmb.edu; bgraimer@utmb.edu

 Subject:
 Follow up to our call on Friday Sept. 10 re Dr. Garg SIO

Date: Thursday, September 16, 2021 9:17:21 AM

Attachments: <u>image001.jpg</u>

Dear Ms. Bremond,

I want to thank you for speaking with me on Friday September 10, 2021 about the issues related to Dr. Nisha Garg in her role as SIO at UTMB. Upon further consideration, my clients and I believe that this process has gone on too long for what was, and is, an honest, nonmaterial mistake. The sham investigation into Dr. Yoon should not have been initiated. Particularly based on an investigation report from an inquiry where Dr. Garg, the Scientific Integrity Committee ("SIC") and others at UTMB repeatedly violated UTMB's PPMIR and multiple sections of 42 CFR part 93. These include 42 CFR §93.301(b)(2), 42 CFR §93.302(a)(2)(i – ii), 42 CFR §93.304(b, e and f), 42 CFR §93.305(b), 42 CFR $\S93.307(a)(1-3)$, 42 CFR $\S93.307(d)(1-2)$, and 42 CFR $\S93.307(e-g)$. Then the fact that no one at UTMB has recognized the inherent and blatant conflict of interest that resulted when the investigation report dated January 2, 2020 was repurposed as an inquiry report by retaining all of the written content other than Dr. Yoon should be fired to support launching a sham investigation run by Dr. Garg. The result is that if Dr. Garg's investigation decides to call for the firing of Dr. Yoon, then the decision looks preordained. If the result is that Dr. Yoon is found innocent, as he is, then Dr. Garg and the Scientific Integrity Committee committed a serious and actionable violation that was not corrected over the last two years. Indeed, the consequence of this malfeasance is something that Dr. Yoon has had to live with for almost two years which has resulted in all of my clients suffering significant physical, mental and emotional damage.

This torture of my clients over the last two years has been inhumane and just cruel. At this point, my clients reasonably have no faith in the objectivity or fairness of any inquiry or investigation handled by anyone associated with UTMB and the UT system. This whole thing should have ended when Dr. Yoon explained in a letter sent in November 2019 to Dr. Garg how the honest mistake occurred. In this same letter, Dr. Yoon also explained in detail the steps that Dr. Yoon and Dr. Louise Prakash undertook to implement procedures that ensure such a mistake could not happen again in the future. This farce should have also ended when the journal published the corrigendum with the corrected figure with no other requirements. By merely publishing the corrigendum, Dr. Yoon's mistake clearly does not meet the requirements of research misconduct as defined in 42 CFR 93.103. Indeed, in reviewing cases where research misconduct has been found, it has been based on purposeful and willful fraud where the scientist knowingly and with willful intent submitted papers based on fake data. You can go to the ORI website to find these cases. That clearly did not happen here.

The mistake was honest and not material. This matter needs to end now. If the decision by you and UTMB is to continue the sham investigation into Dr. Yoon, then I am putting you, Dr. Garg, President Raimer, the SIC and others involved in this matter at UTMB on notice that my clients will take all steps legally available to them to end this matter.

You should feel free to call me, but this torture must end now.

Managing Partner				
Peter D. Weinstein, Ph.D., J.D.				
Peter				
Sincerely,				

Entralta P.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive
Suite 212, PMB 511
Georgetown, TX 78633
P 805-444-7865
F 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

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1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D. Phone: 805-444-7865 Fax: 805-322-4469 peter.weinstein@entralta.com www.entralta.com

September 23, 2021

Daniel H. Sharphorn Vice Chancellor and General Counsel University of Texas 210 West 7th Street Austin, TX 78701 Tel: (512) 499-4462

Fax: (512) 499-4523

dsharphorn@utsystem.edu

Dear Mr. Sharphorn,

I will start by saying that I fully understand that sending this letter to you is out of the ordinary course of business in a matter like the one I will address below. However, it is the last chance I can see that will prevent a lawsuit by my clients Dr. Louise Prakash, Dr. Satya Prakash (collectively "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") against the University of Texas ("UT"), the University of Texas Medical Branch ("UTMB") and multiple individuals from UT and UTMB. The genesis of this matter relates to a botched and dare I say, maliciously handled inquiry into a mistake by Dr. Yoon that has been conducted by Dr. Nisha Garg ("Dr. Garg"), the Scientific Integrity Officer ("SIO") of UTMB. Dr. Garg's malicious efforts have been supported and countenanced by UTMB's legal department and UTMB President Raimer.

This investigation relates to a supplemental figure in a paper published by Drs. Prakash and Dr. Yoon in Genes & Development in 2019. While revising the paper during the publication process, a supplemental figure was added to the paper that did not contain the correct gels. This supplemental figure was not material to the findings, conclusions or results of the paper. When this mistake was pointed out to Drs. Prakash and Dr. Yoon in September 2019, it was immediately corrected and a corrigendum was published by the journal. It is important to note that the publishing journal had no issue with the correction and the paper was not retracted. Additionally, Drs. Prakash and Dr. Yoon implemented procedures to ensure such a mistake would not occur again in the future. This should have ended this matter. Unfortunately, Dr. Garg and others at UTMB had only begun their two-year malevolent process.

Between September and November, 2019 Dr. Garg was made aware in multiple letters of the corrigendum and the changes made in the handling of data going forward in the laboratory of Drs. Prakash. Dr. Garg was also made aware that the mistake was an honest one by Dr. Yoon. However, it is clear from the written record that Dr. Garg either ignored the letters sent to her or did not read them. Instead, Dr. Garg met with the Scientific Investigation Committee ("SIC") to



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investigate Drs. Prakash and Dr. Yoon. The committee met in December, 2019 and in January, 2020 prepared and sent to Dr. Garg an Investigation Report. The Investigation Report called for Dr. Yoon to be terminated immediately. What is interesting is that the Investigation Report also stated that changes were to be made in handling of data in Drs. Prakash's lab, changes that had been implemented months before the SIC met and detailed in the aforementioned letters. This suggests that Dr. Garg failed to provide the written communications containing the exculpatory information provided by Drs. Prakash and Dr. Yoon to Dr. Garg between September and November, 2019 to the SIC, which met in December 2019.

The report was provided to Drs. Prakash and Dr. Yoon in February, 2020. In response, in March, 2020 Drs. Prakash and Dr. Yoon sent Dr. Garg a letter setting forth that Dr. Garg's "investigation" had violated the UTMB' Policy and Procedure Manual of Integrity in Research ("PPMIR"). Our subsequent review has also determined that she also violated multiple sections of 42 CFR § part 93 and the UT Regents Code of Conduct. These include, at a minimum, 42 CFR §93.301(b)(2), 42 CFR §93.302(a)(2)(i – ii), 42 CFR §93.304(b, e and f), 42 CFR §93.305(b), 42 CFR §93.307(a)(1 – 3), 42 CFR §93.307(d)(1 – 2), and 42 CFR §93.307(e – g) and Regents Rules of Conduct Rule 30103 and 30602. The latter violations were identified and pointed out to Dr. Garg, UTMB's legal department and President Raimer on July 26, 2021 and September 16, 2021. To date none of the aforementioned individuals or departments has taken any action to remedy this situation

After sending the March, 2020 letter Drs. Prakash and Dr. Yoon did not hear from Dr. Garg for a year. Then in March, 2021 Dr. Garg sent an email asking Dr. Louise Prakash to confirm that she had fired Dr. Yoon. Drs. Prakash responded a couple of days later stating that they found Dr. Garg's email "perplexing" and pointed out how surprised they were that Dr. Garg had ignored the issues with her investigation detailed in their March, 2020 letter. It was about two and half months later that Dr. Garg wrote to Drs. Prakash and Dr. Yoon that she realized that a mistake had been made in labelling the report by the SIC an "Investigation Report." Dr. Garg then wrote that the "Investigation Report" would now be called an "Inquiry Report," with the only difference being that she had taken out Section 4, which called for Dr. Yoon to be fired. This "Inquiry Report" was sent to UTMB President Raimer who approved the implementation of a formal investigation of Dr. Yoon.

What happened here is flawed in so many ways. First, the process followed by Dr. Garg and UTMB President Raimer still continued to violate the inquiry process set forth in the UTMB PPMIR, several sections of 42 CFR part 93, and the Regents Rules of Conduct. Next, it does not take a genius to determine that removing the conclusion from the original "Investigation Report" and relabeling it an "Inquiry Report" creates an inherent conflict of interest. Either Dr. Garg's investigation finds Dr. Yoon guilty and declares he should be fired, so that the investigation process reasonably appears to have come to a preordained conclusion, or Dr. Yoon is found rightfully innocent and Dr. Garg, UTMB's legal department and UTMB President Raimer have put Dr. Yoon as well as Drs. Prakash through an unwarranted and malicious two-year hell period, with the damage it created. Amazingly, as of the date of this letter neither Dr. Garg,



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UTMB's legal department, or UTMB President Raimer have conceded this conflict of interest even after it was pointed out to them.

So continuing the hell-scape drama, at the end of June, Dr. Garg let Drs. Prakash and Dr. Yoon know that the investigation of Dr. Yoon was now official per the decision of UTMB President Raimer and that Drs. Prakash were to produce papers and grants for the last five years that included Dr. Yoon. At this point, I intervened on behalf of Drs. Prakash and Dr. Yoon and sent Dr. Garg a long letter on July 26, 2021 detailing all of the issues with the handling of this matter by her, UTMB's Legal Department (e.g. Carolee A. King) and President Raimer. I included the aforementioned correspondence as attachments to that letter. I have attached my July 26, 2021 letter with its attachments to the email. It was not until September 2, 2021 that Dr. Garg responded to my letter. In her letter she ignored everything I had stated about her failures to follow the PPMIR and her violations of the UT Regents Code of Conduct. She stated that the investigation would continue under her direction.

At this point it was clear that it did not matter to Dr. Garg or anyone at UTMB that the process they were following violated UTMB's PPMIR, several sections of 42 CFR part 93 and the UT Regents Code of Conduct. Knowing that my clients could not receive fair treatment at UTMB and that everyone from UTMB President Raimer and UTMB's Legal Department on down were biased, prejudiced and clearly did not care that they were causing Drs. Prakash and Dr. Yoon great harm and cognizable damage, I then reached out to Ana Vieira Ayala, Assistant General Counsel in the UT General Counsel's Office on September 10, 2021. I left Ms. Ayala a voice mail asking her to call me as I wanted to discuss serious issues related to my clients at UTMB. Though I did not explicitly state that I was making the call as a Whistle Blower, I fully expected that she would call me back so I could discuss this matter with her. I also reasonably believed that Ms. Ayala understood and appreciated that my message constituted one by a Whistle Blower. Instead, Ms. Ayala contacted Ms. Bremond who heads UTMB's litigation group. I was and continued to be surprised that Ms. Ayala took this step without calling me first to find out why I had called. It has had the effect of "outing the Whistle Blower" and making matters worse for Drs. Prakash and Dr. Yoon at UTMB.

So, Ms. Bremond called me on September 10, 2021 and was impatient and generally pretty nasty. I also believe that she lied to me during the call about her knowledge of the matter regarding Drs. Prakash and Dr. Yoon. After my call with Ms. Bremond, I expected to hear back from her within a few days that Dr. Garg was no longer running the investigation. Surprisingly, I have heard nothing. This prompted me on September 16, 2021 to send Ms. Bremond an email stating that my clients had reached the end of their rope and that this entire process had to end or my clients would have to take any legal and administrative actions available to them. As of today, I still have heard nothing from Ms. Bremond or anyone else at UTMB.

So this brings me to the reason I have sent this letter to you. It is clear to me that there is no means of receiving a fair and nonprejudicial resolution to this matter with anyone at UTMB. In our eyes they are all corrupted. Thus, I am sending this letter to you in a last hope to resolve this



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matter short of litigation. It is my hope that you can intervene in this matter and put things right. That would mean at a minimum, immediately moving this matter out of UTMB and reasonably closing it expeditiously following an unbiased, nonprejudicial review of the facts. Anything less is unacceptable to Drs. Prakash and Dr. Yoon. In the end, Drs. Prakash and Dr. Yoon have suffered great emotional, physical, reputational and other damages; including, this whole malicious matter having a negative effect on their ability to conduct their research. It is our hope that you can end their suffering.

As a courtesy, I have attached the correspondence and the Investigation Report to this letter for your review if you do not already have them. I look forward to your prompt reply and if necessary, I am available to meet you in person to resolve this matter.

Best regards,

Peter D. Weinstein

Enclosures

From: Sharphorn, Dan
To: Peter Weinstein

Subject: RE: Letter regarding UTMB matter - Potential Federal Court Litigation

Date: Friday, September 24, 2021 11:30:37 AM

Attachments: image002.png

I have received your letter and attachments.

Daniel H. Sharphorn
Vice Chancellor and General Counsel
The University of Texas System
210 West 7th Street
Austin, Texas 78701
512-499-4462

dsharphorn@utsystem.edu



From: Peter Weinstein <peter.weinstein@entralta.com>

Sent: Thursday, September 23, 2021 1:17 PMTo: Sharphorn, Dan <dsharphorn@utsystem.edu>Cc: Peter Weinstein <peter.weinstein@entralta.com>

Subject: Letter regarding UTMB matter - Potential Federal Court Litigation

EXTERNAL MAIL

This email originated outside of The University of Texas System Administration. Please exercise caution when clicking on links or opening attachments.

Dear Mr. Sharphorn,

Please find my letter to you regarding a serious matter that requires resolution at UTMB. Once you have read my letter and the accompanying documents, please feel free to contact me directly to discuss. This matter has been going on too long and requires a timely and reasonable resolution, so I would ask that you respond to me no later than October 1, 2021. In the interim, please confirm receipt of this email and the accompanying attachments. If I do not hear from you by October 1, I will assume that my clients will be required to take this matter to Federal Court to obtain a fair and reasonable resolution.

Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D. Managing Partner



Entralta P.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive
Suite 212, PMB 511
Georgetown, TX 78633
P 805-444-7865
F 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

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Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D.
Phone: 805-444-7865
Fax: 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

BY EMAIL October 4, 2021

Daniel H. Sharphorn Vice Chancellor and General Counsel University of Texas 210 West 7th Street Austin, TX 78701 Tel: (512) 499-4462

Fax: (512) 499-4523 dsharphorn@utsystem.edu

Dear Mr. Sharphorn,

I want to thank you for speaking with me on Thursday October 1, 2021. I am sending this letter in response to that call to memorialize several points we discussed. First, it is my understanding that Dr. Nisha Garg is no longer responsible for an investigation into my clients Dr. Louise Prakash, Dr. Satya Prakash and Dr. Jung-Hoon Yoon. I also understand that the investigation led by Dr. Garg has been terminated. Thus, I am confirming that there are no outstanding requests that my clients need to respond to at this time.

It is further my understanding that a new individual will be brought in to replace Dr. Garg who will be tasked with launching a new, *de novo* inquiry. Now with regard to what is to be done next, I note that during our call you referred to the new effort by this new individual as an investigation. However, I want to be clear that I believe that what you meant was that the new individual would be starting over with a new inquiry to determine if an investigation should even be initiated pursuant to the UTMB PPMIR and 42 CFR Part 93.

As I stated during our call, my clients and I do not believe that a fair inquiry, let alone an investigation can be conducted by anyone at UTMB once President Raimer provided his approval to Dr. Garg to initiate an investigation. Everyone at UTMB who would replace Dr. Garg, and those who would participate as a member of the Scientific Integrity Committee, which is to be appointed pursuant to the UTMB PPMIR, ultimately reports to President Raimer. Thus, there is an inherent conflict in that for the new individual and members of the SIC to do the right thing, they would have to contradict their boss, President Raimer and determine he made a material mistake by agreeing with Dr. Garg to initiate the highly flawed investigation. The inherent conflict is that if they decide to initiate an investigation, my clients and I will reasonably



believe that this decision was preordained. However, I understand from our call that you will proceed with the inquiry with personnel drawn from UTMB despite my client concerns.

Finally, as a courtesy, I would appreciate if you could let me know when you have selected someone to replace Dr. Garg and when they intend to initiate a new inquiry.

Best regards,

Peter D. Weinstein



Department of Legal Affairs

Carolanda Bremond Woodgett, Associate Vice President Direct Dial: 409-747-8735 Fax: 409-747-8741

cabremon@utmb.edu

October 11, 2021

VIA E-MAIL

Peter D. Weinstein, PhD, JD Managing Partner Entralta P.C. 4500 Williams Drive Suite 212, PMB 511 Georgetown, TX 78633

Re: Louise Prakash, PhD, Satya Prakash, PhD, and Jung-Hoon Yoon, PhD

Dear Mr. Weinstein:

This correspondence is in response to our September 10, 2021 conversation as well as your September 16, 2021 correspondence. As you were previously advised, The University of Texas Medical Branch at Galveston ("UTMB") is a recipient of Public Health Service ("PHS") funds under 42 CFR Parts 50 and 93. Accordingly, UTMB has an "affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work and has primary responsibility for responding to and reporting allegations of research misconduct."

During our September 10, 2021 conversation, you acknowledged UTMB's obligation to conduct an inquiry into the reported actions of your clients, Louise Prakash, PhD ("Prakash"), Satya Prakash, PhD ("Prakash"), and Jung-Hoon Yoon, PhD ("Yoon") as required by the Office of Research Integrity's Division of Investigative Oversight. However, you requested that UTMB engage an independent party to conduct the investigation.

Since we last spoke, UTMB has appointed David W. Niesel, PhD as its Scientific Integrity Officer effective October 5, 2021. Dr. Niesel joined the faculty at UTMB in the Department of Microbiology and Immunology in 1983 and became the Department Chairman. In 1997, Dr. Niesel became the Vice Dean of UTMB's Graduate School of Biomedical Sciences. Thereafter, he was appointed as Vice President and Dean of UTMB's Graduate School of Biomedical Sciences and later Senior Vice President and Chief Research Officer. He assumed the Associate Chief Research Officer position in September 2018 and served in that role until his

Mr. Weinstein October 11, 2021 Page **2** of **2**

retirement from UTMB in January 2021. Since January 2021, he has served as a part-time adjunct professor in the Graduate School of Biomedical Sciences.

In addition, UTMB has requested the assistance of The University of Texas System's Vice Chancellor and General Counsel Daniel H. Sharphorn, JD. Specifically, Mr. Sharphorn has been asked to provide Dr. Niesel and the UTMB scientific integrity program staff with advice and counsel on relevant federal research integrity regulations and guidelines including, but not limited to, 42 C.F.R. Part 93.

With these changes in place, Dr. Niesel will re-initiate the research misconduct review process, beginning with the assessment and inquiry phases as you requested during our September 10, 2021 conversation. As such, the previous January 2, 2020 investigation report will be disregarded. Upon completion of the assessment, Dr. Niesel may be in touch with your client, Dr. Yoon, to initiate the inquiry phase. Please note that if this matter proceeds to the inquiry phase, Dr. Yoon's cooperation as the Respondent and Drs. Prakashs' cooperation as witnesses are a condition of their continued employment. Specifically, as you were previously advised, UTMB's Policy and Procedure Manual on Integrity in Research states, "Institutional members will cooperate with the [Scientific Integrity Officer] and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the SIO or other institutional officials." Furthermore, such failure or refusal will require reporting to ORI and the National Institutes of Health, the funding agency of the grants, for additional action.

I hope this correspondence addresses your immediate concerns.

Very truly yours,

CBWoodgett

Carolanda Bremond Woodgett

CB/mc

Subject: A Message from the President and the EVP, Provost and Dean, SOM

Date: Thursday, October 14, 2021 4:32:54 PM

Attachments: image001.png



Oct. 14, 2021

We are pleased to share that David W. Niesel, PhD, will serve as Scientific Integrity Officer (SIO) effective Oct. 15, 2021. As SIO, he will have primary responsibility for adherence to the institution's policies and procedures on research misconduct.

Dr. Niesel has been a leader in UTMB's Research Enterprise for many years. He joined UTMB in 1983 and held leadership roles, including Chief Research Officer and Dean of the Graduate School of Biomedical Sciences, and was a Professor in the Department of Microbiology and Immunology. He retired in January 2021 and has continued to serve as an adjunct faculty member in Microbiology and Immunology.

We are confident in Dr. Niesel's leadership, and we appreciate his service in this extremely important role. Thanks also to Nisha Garg, PhD, for her past service as SIO.

Sincerely yours,

Ben G. Raimer, MD, MA, FAAP President

Charles P. Mouton, MD, MS, MBA Executive Vice President, Provost and Dean, School of Medicine

Thomas N. and Gleaves T. James Distinguished Chair

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Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D.
Phone: 805-444-7865
Fax: 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

October 25, 2021

Alexander Runko, Ph.D.
Director
Division of Investigative Oversight
Office of Research Integrity
1100 Wooten Parkway
Suite 240
Rockville, MD, 20852
Tel: (240) 453-8800
Alexander.runko@hhs.gov

Dear Dr. Runko,

I am sending this letter to you to bring to your attention the illegal behavior, gross negligence and willful misconduct of Dr. Nisha Garg ("Dr. Garg"), the now former Scientific Integrity Officer ("SIO") of the University of Texas Medical Branch ("UTMB") located in Galveston. As you are aware, my clients Dr. Louise Prakash and Dr. Satya Prakash (collectively, hereinafter referred to as "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") have been subjected to an over two-year long "investigations" led by Dr. Garg, which still continues against Dr. Yoon.

After over two years of Dr. Garg's "investigations," my clients engaged me to help defend them. As will be described in more detail below, I tried to reason with Dr. Garg shortly after my engagement. I raised all of the issues that Drs. Prakash and Dr. Yoon had previously brought to her attention in written communications in November 2019, and March 2020, that relate to her illegal behavior, gross negligence and willful misconduct, including the violation of UTMB's Policy and Procedure Manual of Integrity in Research ("PPMIR"). In particular, the PPMIR sets forth the process of first an inquiry and then, if warranted, an investigation. The PPMIR also sets forth the rights of the accused during the inquiry and then the investigation process. Dr. Garg failed to follow any of the process or other rules in the PPMIR during the over two-year period of her investigations, which started in May 2019 and recently ended in October 2021. I also raised additional concerns based on her violation of the UTMB Regents Code of Conduct and her violations of 42 CFR Part 93 in July 2021 and September 2021 written communications sent by me. However, despite having her failings pointed out to her on multiple occasions, she continued to move forward with her never ending "investigations."

Dr. Garg's failure to listen to reason forced me to raise her illegal actions, other failures, and her unethical and immoral behavior with Daniel Sharphorn, Vice Chancellor and General Council of the University of Texas System. (Letter to UT GC Sharphorn attached as Exhibit A). I am not



sure you are aware, but Dr. Garg is no longer the SIO of UTMB, which we reasonably believe is due to my clients' raising their issues with her handling of the "investigations" over the last over two plus years to General Counsel Sharphorn. (Announcement of Dr. Niesel as UTMB's new SIO attached as Exhibit B). Additionally, with her termination as SIO, Dr. Garg's latest "investigation" has been terminated and a new inquiry initiated with the new SIO at UTMB. (Email from C. B. Woodgett attached as Exhibit C). Though my clients do not believe such an inquiry is merited and have serious and reasonable concerns about the fairness of any inquiry run out of UTMB, they believe that this inquiry will come to the result that should have happened two years ago – the mistake was an honest one and did not rise to the level of research misconduct.

Now, as will be discussed in more detail below, during her over two-year "investigations" (I contend actually three attempts at the inquiry/investigation process¹), Dr. Garg has repeatedly violated UTMB's PPMIR. Dr. Garg has also repeatedly violated multiple sections of 42 CFR § part 93. Dr. Garg continued with this behavior even after her violations were specifically and explicitly pointed out to her and others at UTMB. My clients and I also reasonably believe that Dr. Garg's purposefully and repeatedly failed to inform you and likely others at the National Institute of Health ("NIH") Office of Research Integrity ("ORI") of my client's and my written communications to Dr. Garg that pointed out in clear language her failures and illegal behavior. My clients and I reasonably believe that Dr. Garg failed to share our written communications with the NIH ORI in order to obtain the ORI's alleged request to initiate an investigation into Dr. Yoon. (Dr. Garg letter September 1, 2020, attached as Exhibit D)

It is because of the complete loss of institutional control over Dr. Garg and her clear bias and prejudice against Drs. Prakash and Dr. Yoon that I take this extraordinary action and reach out to you directly so that you and the NIH ORI are aware that Dr. Garg has committed fraud and other illegal actions (including violations of UTMB's PPMIR, the University of Texas's Regents Code of Conduct and several sections of 42 CFR Part 93) against the NIH ORI and my clients. We believe that these actions require that the NIH ORI initiate an immediate inquiry and investigation into the actions of Dr. Garg and those who supported her. My clients and I also believe that the NIH ORI should take all actions available to bring some semblance of justice to this seriously unfortunate situation. We make this request based in part on the damage that Dr. Garg's illegal, malicious and willful actions have caused Drs. Prakash and Dr. Yoon. Each has suffered great mental, emotional and physical stress over the last two years for a situation that should have ended long ago. Dr. Garg's actions have also seriously and will continue to cause reputational harm to the detriment of Drs. Prakash and Dr. Yoon. Finally, Dr. Garg's actions

¹ Drs. Prakash and Dr. Yoon reasonably believe that the first sham investigation started in May 2019 and went until May 2021, when it appears Dr. Garg finally read the email from Dr. Louise Prakash from March 2021 and Drs. Prakash and Dr. Yoon from March 2020. The second sham investigation started in June 2021, with the letter from Dr. Garg to Dr. Louise Prakash telling her that the Investigation Report was now an inquiry report, and the investigation was approved by UTMB President Raimer and the third sham investigation started on September 12, 2021 with the letter from Dr. Garg to Dr. Peter D. Weinstein.



have led Drs. Prakash to have concerns about how this matter will affect their ability to continue to receive research grants from the NIH.

Now, I am sending this letter to you in part because in Dr. Garg's letter to me on September 1, 2021 (attached to this email as Exhibit D), she personally implicates the NIH ORI as formally instructing her to initiate the third "investigation" by claiming that the NIH ORI told her to use her January 2, 2020, Investigation Report as the basis to initiate a new investigation. According to Dr. Garg, the NIH ORI instructed her to remove the judgment to fire Dr. Yoon from the January 2, 2020, Investigation Report and relabel the Investigation Report an Inquiry Report. Specifically, Dr. Garg states in her September 1 letter that:

"UTMB has been in communication with the Office of Research Integrity ("ORI"), which oversees scientific integrity on behalf of the Secretary of Health and Human Services and has been advised by ORI's Division of Investigative Oversight ("DIO") to proceed with the investigation into Dr. Yoon by treating the mislabeled "Investigation Report" dated January 2, 2020 as an "Inquiry Report" and disregarding the recommendations contained therein as premature." (emphasis added)

I do not know if you and the ORI actually told Dr. Garg to initiate the investigation into Dr. Yoon, but if you did, it is my belief along with that of Drs. Prakash and Dr. Yoon that this decision was made because Dr. Garg failed to provide the NIH ORI DIO with all of the relevant information.

To give you some background, I am attaching the letter I sent to Dr. Garg on July 26, 2021, that sets forth in great detail many of Dr. Garg's violations (my July 26, 2021, letter attached to this email as Exhibit E). Attached to the July 26 letter are correspondence starting in September 2019 and going through June 2021 between Dr. Garg and Dr. Louise Prakash, Dr. Satya Prakash and Dr. Yoon. I would ask you as a courtesy to read my letter to Dr. Garg and the attached correspondence. What you will find is that by November 2020, my clients had explained that the mistake was an honest one and that they had already taken steps to ensure it could not happen again. Additionally, the mistake was not material to the results, findings, and conclusions of the published paper. In fact, the journal Genes and Development had allowed them to correct the mistake through the publication of a corrigendum².

Further, it is clear through her actions since November 2019, that Dr. Garg either did not read the written communications from my clients that were attached to my July 26, 2021, letter or purposefully ignored them. My letter details Dr. Garg's failure to follow the UTMB PPMIR inquiry. My letter further points out that even after Dr. Garg was appraised of her violations of the UTMB PPMIR by Drs. Prakash and Dr. Yoon in March 2020, she ignored her violations and

² It is noteworthy that the journal Genes and Development has recently published a new paper recently submitted by Drs. Prakash and Dr. Yoon. From this it is clear that the journal that published the correction does not believe that Dr. Yoon committed research misconduct as it begs reality that f the publishers had that belief that they would have agreed to publish their new paper.



then willfully continued to violate the procedures of the UTMB PPMIR by continuing with her sham inquiry and investigation. Next, as stated in my letter, Dr. Garg's actions violated the University of Texas' Regents Code of Conduct.

Additionally, though not addressed in my letter to Dr. Garg, but addressed later in an email to Carolanda Bremond Woodgett, Head of Litigation at UTMB, Dr. Garg's failures further violated federal law. More particularly, Dr. Garg violated multiple sections of 42 CFR Part 93. For instance, Dr. Garg has clearly violated and continues to violate at a minimum: 42 CFR §93.301(b)(2), 42 CFR §93.302(a)(2)(i – ii), 42 CFR §93.304(b, e and f), 42 CFR §93.305(b), 42 CFR §93.307(a)(1 – 3), 42 CFR §93.307(d)(1 – 2), and 42 CFR §93.307(e – g).

Based on all the evidence, it is immutable that Dr. Garg is not an ethical or moral person and had no issue continuing with her sham "investigations" despite her misguided actions being repeatedly pointed out to her. In this regard, beyond her failures and violations of the UTMB PPMIR, 42 CFR § part 93 and the University of Texas' Regents Code of Conduct, it is Dr. Garg's ethical and moral failures that also needs to be looked into by the NIH ORI. Indeed, one has to wonder whether based on her repeated and willful failures and material violations, Dr. Garg should be allowed to continue to receive NIH grant funding. With her recent termination as SIO, it is clear that even UTMB no longer finds that she is fit to continue in her former role based on her past behavior. In fact, in law, UTMB's termination (constructive or actual) as SIO should be considered an admission against interest. In simple terms this means that UTMB found Dr. Garg's actions in her dealings with Drs. Prakash and Dr. Yoon raiseable enough to have terminated her as SIO.

In the end, what gets lost in Dr. Garg's ethical, moral and material failures, illegal actions and other violations is that this whole affair has been over an honest mistake by Dr. Yoon. As stated, it is incontrovertible that Dr. Yoon's mistake was neither material to the results, findings or conclusions of the paper. In fact, the publishing journal merely corrected it with a corrigendum. Additionally, as Dr. Garg is aware, immediately upon learning of Dr. Yoon's honest mistake, Dr. Yoon and Dr. Louise Prakash immediately put into effect new procedures to ensure a similar mistake would not be made again. Dr. Garg was made aware of these new procedures in a letter from Dr. Yoon in November 2019 prior to her initiating the improper "investigation" in December 2019, that resulted in the January 2, 2020, Investigation Report. However, based on the January 2, 2020, Investigation Report it is clear that Dr. Garg purposefully failed to provide Drs. Prakash's and Dr. Yoon's exculpatory evidence that they had provided to Dr. Garg to the UTMB Scientific Integrity Committee ("SIC") that prepared the Investigation Report. The result was that the SIC in the January 2, 2020 communication recommended that Dr. Louise Prakash institute a policy to make sure the honest mistake did not occur again. However, this policy had already been implemented as disclosed to Dr. Garg by Dr. Yoon in his November 2019 letter. Thus, it is clear that this letter, and likely none of the other written communications provided by Drs. Prakash and Dr. Yoon were provided to the SIC before they prepared their improper January 2, 2020, Investigation Report.



Finally, I understand that the NIH ORI has discretion over whether to take action against Dr. Garg based on the allegations made in this letter and the supporting evidence. However, it is the belief of Drs. Prakash, Dr. Yoon and myself that based on the evidence I have provided and UTMB's own action in terminating her as SIO that there is sufficient justification for the NIH ORI to look into this matter and take all appropriate actions.

I appreciate your time in reviewing this letter and the attachments hereto. If you have any questions, you should feel free to reach out to me directly. I can also put you in touch with Dr. Louise Prakash, Dr. Satya Prakash or Dr. Yoon.

Best regards,

Peter D. Weinstein

Enclosures

Exhibit A

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1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D. Phone: 805-444-7865 Fax: 805-322-4469 peter.weinstein@entralta.com www.entralta.com

September 23, 2021

Daniel H. Sharphorn Vice Chancellor and General Counsel University of Texas 210 West 7th Street Austin, TX 78701 Tel: (512) 499-4462

Fax: (512) 499-4523

dsharphorn@utsystem.edu

Dear Mr. Sharphorn,

I will start by saying that I fully understand that sending this letter to you is out of the ordinary course of business in a matter like the one I will address below. However, it is the last chance I can see that will prevent a lawsuit by my clients Dr. Louise Prakash, Dr. Satya Prakash (collectively "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") against the University of Texas ("UT"), the University of Texas Medical Branch ("UTMB") and multiple individuals from UT and UTMB. The genesis of this matter relates to a botched and dare I say, maliciously handled inquiry into a mistake by Dr. Yoon that has been conducted by Dr. Nisha Garg ("Dr. Garg"), the Scientific Integrity Officer ("SIO") of UTMB. Dr. Garg's malicious efforts have been supported and countenanced by UTMB's legal department and UTMB President Raimer.

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What happened here is flawed in so many ways. First, the process followed by Dr. Garg and UTMB President Raimer still continued to violate the inquiry process set forth in the UTMB PPMIR, several sections of 42 CFR part 93, and the Regents Rules of Conduct. Next, it does not take a genius to determine that removing the conclusion from the original "Investigation Report" and relabeling it an "Inquiry Report" creates an inherent conflict of interest. Either Dr. Garg's investigation finds Dr. Yoon guilty and declares he should be fired, so that the investigation process reasonably appears to have come to a preordained conclusion, or Dr. Yoon is found rightfully innocent and Dr. Garg, UTMB's legal department and UTMB President Raimer have put Dr. Yoon as well as Drs. Prakash through an unwarranted and malicious two-year hell period, with the damage it created. Amazingly, as of the date of this letter neither Dr. Garg,



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UTMB's legal department, or UTMB President Raimer have conceded this conflict of interest even after it was pointed out to them.

So continuing the hell-scape drama, at the end of June, Dr. Garg let Drs. Prakash and Dr. Yoon know that the investigation of Dr. Yoon was now official per the decision of UTMB President Raimer and that Drs. Prakash were to produce papers and grants for the last five years that included Dr. Yoon. At this point, I intervened on behalf of Drs. Prakash and Dr. Yoon and sent Dr. Garg a long letter on July 26, 2021 detailing all of the issues with the handling of this matter by her, UTMB's Legal Department (e.g. Carolee A. King) and President Raimer. I included the aforementioned correspondence as attachments to that letter. I have attached my July 26, 2021 letter with its attachments to the email. It was not until September 2, 2021 that Dr. Garg responded to my letter. In her letter she ignored everything I had stated about her failures to follow the PPMIR and her violations of the UT Regents Code of Conduct. She stated that the investigation would continue under her direction.

At this point it was clear that it did not matter to Dr. Garg or anyone at UTMB that the process they were following violated UTMB's PPMIR, several sections of 42 CFR part 93 and the UT Regents Code of Conduct. Knowing that my clients could not receive fair treatment at UTMB and that everyone from UTMB President Raimer and UTMB's Legal Department on down were biased, prejudiced and clearly did not care that they were causing Drs. Prakash and Dr. Yoon great harm and cognizable damage, I then reached out to Ana Vieira Ayala, Assistant General Counsel in the UT General Counsel's Office on September 10, 2021. I left Ms. Ayala a voice mail asking her to call me as I wanted to discuss serious issues related to my clients at UTMB. Though I did not explicitly state that I was making the call as a Whistle Blower, I fully expected that she would call me back so I could discuss this matter with her. I also reasonably believed that Ms. Ayala understood and appreciated that my message constituted one by a Whistle Blower. Instead, Ms. Ayala contacted Ms. Bremond who heads UTMB's litigation group. I was and continued to be surprised that Ms. Ayala took this step without calling me first to find out why I had called. It has had the effect of "outing the Whistle Blower" and making matters worse for Drs. Prakash and Dr. Yoon at UTMB.

So, Ms. Bremond called me on September 10, 2021 and was impatient and generally pretty nasty. I also believe that she lied to me during the call about her knowledge of the matter regarding Drs. Prakash and Dr. Yoon. After my call with Ms. Bremond, I expected to hear back from her within a few days that Dr. Garg was no longer running the investigation. Surprisingly, I have heard nothing. This prompted me on September 16, 2021 to send Ms. Bremond an email stating that my clients had reached the end of their rope and that this entire process had to end or my clients would have to take any legal and administrative actions available to them. As of today, I still have heard nothing from Ms. Bremond or anyone else at UTMB.

So this brings me to the reason I have sent this letter to you. It is clear to me that there is no means of receiving a fair and nonprejudicial resolution to this matter with anyone at UTMB. In our eyes they are all corrupted. Thus, I am sending this letter to you in a last hope to resolve this



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As a courtesy, I have attached the correspondence and the Investigation Report to this letter for your review if you do not already have them. I look forward to your prompt reply and if necessary, I am available to meet you in person to resolve this matter.

Best regards,

Peter D. Weinstein

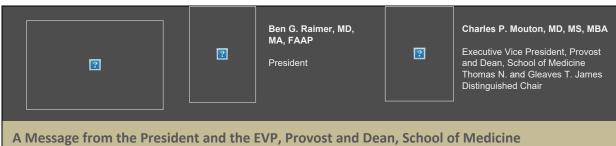
Enclosures

Exhibit A

Subject: A Message from the President and the EVP, Provost and Dean, SOM

Date: Thursday, October 14, 2021 4:32:54 PM

Attachments: image001.png



Oct. 14, 2021

We are pleased to share that David W. Niesel, PhD, will serve as Scientific Integrity Officer (SIO) effective Oct. 15, 2021. As SIO, he will have primary responsibility for adherence to the institution's policies and procedures on research misconduct.

Dr. Niesel has been a leader in UTMB's Research Enterprise for many years. He joined UTMB in 1983 and held leadership roles, including Chief Research Officer and Dean of the Graduate School of Biomedical Sciences, and was a Professor in the Department of Microbiology and Immunology. He retired in January 2021 and has continued to serve as an adjunct faculty member in Microbiology and Immunology.

We are confident in Dr. Niesel's leadership, and we appreciate his service in this extremely important role. Thanks also to Nisha Garg, PhD, for her past service as SIO.

Sincerely yours,

Ben G. Raimer, MD, MA, FAAP President

Charles P. Mouton, MD, MS, MBA Executive Vice President, Provost and Dean, School of Medicine

Thomas N. and Gleaves T. James Distinguished Chair

Exhibit C

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 215 of 514



Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D.
Phone: 805-444-7865
Fax: 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

September 23, 2021

Daniel H. Sharphorn Vice Chancellor and General Counsel University of Texas 210 West 7th Street Austin, TX 78701 Tel: (512) 499-4462

Fax: (512) 499-4402

dsharphorn@utsystem.edu

Dear Mr. Sharphorn,

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Letter to Univ. of Texas General Counsel Sharphorn September 23, 2021

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Letter to Univ. of Texas General Counsel Sharphorn September 23, 2021

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As a courtesy, I have attached the correspondence and the Investigation Report to this letter for your review if you do not already have them. I look forward to your prompt reply and if necessary, I am available to meet you in person to resolve this matter.

Best regards,

Peter D. Weinstein

Enclosures

Exhibit D



Department of Legal Affairs

Carolanda Bremond Woodgett, Associate Vice President Direct Dial: 409-747-8735 Fax: 409-747-8741

rax: 409-747-8741 cabremon@utmb.edu

October 11, 2021

VIA E-MAIL

Peter D. Weinstein, PhD, JD Managing Partner Entralta P.C. 4500 Williams Drive Suite 212, PMB 511 Georgetown, TX 78633

Re: Louise Prakash, PhD, Satya Prakash, PhD, and Jung-Hoon Yoon, PhD

Dear Mr. Weinstein:

This correspondence is in response to our September 10, 2021 conversation as well as your September 16, 2021 correspondence. As you were previously advised, The University of Texas Medical Branch at Galveston ("UTMB") is a recipient of Public Health Service ("PHS") funds under 42 CFR Parts 50 and 93. Accordingly, UTMB has an "affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work and has primary responsibility for responding to and reporting allegations of research misconduct."

During our September 10, 2021 conversation, you acknowledged UTMB's obligation to conduct an inquiry into the reported actions of your clients, Louise Prakash, PhD ("Prakash"), Satya Prakash, PhD ("Prakash"), and Jung-Hoon Yoon, PhD ("Yoon") as required by the Office of Research Integrity's Division of Investigative Oversight. However, you requested that UTMB engage an independent party to conduct the investigation.

Since we last spoke, UTMB has appointed David W. Niesel, PhD as its Scientific Integrity Officer effective October 5, 2021. Dr. Niesel joined the faculty at UTMB in the Department of Microbiology and Immunology in 1983 and became the Department Chairman. In 1997, Dr. Niesel became the Vice Dean of UTMB's Graduate School of Biomedical Sciences. Thereafter, he was appointed as Vice President and Dean of UTMB's Graduate School of Biomedical Sciences and later Senior Vice President and Chief Research Officer. He assumed the Associate Chief Research Officer position in September 2018 and served in that role until his

Mr. Weinstein October 11, 2021 Page **2** of **2**

retirement from UTMB in January 2021. Since January 2021, he has served as a part-time adjunct professor in the Graduate School of Biomedical Sciences.

In addition, UTMB has requested the assistance of The University of Texas System's Vice Chancellor and General Counsel Daniel H. Sharphorn, JD. Specifically, Mr. Sharphorn has been asked to provide Dr. Niesel and the UTMB scientific integrity program staff with advice and counsel on relevant federal research integrity regulations and guidelines including, but not limited to, 42 C.F.R. Part 93.

With these changes in place, Dr. Niesel will re-initiate the research misconduct review process, beginning with the assessment and inquiry phases as you requested during our September 10, 2021 conversation. As such, the previous January 2, 2020 investigation report will be disregarded. Upon completion of the assessment, Dr. Niesel may be in touch with your client, Dr. Yoon, to initiate the inquiry phase. Please note that if this matter proceeds to the inquiry phase, Dr. Yoon's cooperation as the Respondent and Drs. Prakashs' cooperation as witnesses are a condition of their continued employment. Specifically, as you were previously advised, UTMB's Policy and Procedure Manual on Integrity in Research states, "Institutional members will cooperate with the [Scientific Integrity Officer] and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the SIO or other institutional officials." Furthermore, such failure or refusal will require reporting to ORI and the National Institutes of Health, the funding agency of the grants, for additional action.

I hope this correspondence addresses your immediate concerns.

Very truly yours,

CBWoodgett

Carolanda Bremond Woodgett

CB/mc

Exhibit E



Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D. Phone: 805-444-7865 Fax: 805-322-4469

July 26, 2021

Nisha Jain Garg, Ph.D., MBA Scientific Integrity Officer Professor, Microbiology and Immunology University of Texas Medical Branch, Galveston O: 409-7476865

E: nigarg@utmb.edu

RE: Response to Investigation of Drs. Louise, Satya Prakash and Dr. Jung-Hoon Yoon

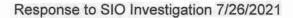
Dear Dr. Garg,

I have been engaged by Drs. Louise and Satya Prakash (individually, "Dr. L. Prakash" and "Dr. S. Prakash" and collectively, the "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") to represent them regarding the investigation undertaken by you on behalf of the University of Texas Medical Branch, Galveston ("UTMB") as UTMB's Scientific Integrity Officer ("SIO") regarding the genesis of Supplementary Figure 2 ("Figure S2") that was published in Genes & Development 33:282 – 287 (2019) (the "G & D paper").

I understand that your investigation started based on a complaint filed by a former member of the Prakash lab group who worked with Drs. Prakash. This complaint was filed with you as SIO in May 2019 and claimed that Figure S2 did not include the right gels.

I also understand that upon learning of the mistake regarding Figure S2 on or about September 2019, Dr. Yoon reran the experiments and then took the new gels to create a substitute Figure S2. This substitute Figure S2 was sent to G & D to be published as a Corrigendum. I understand that the substitute Figure S2 was accepted and published as a Corrigendum by G & D. I understand that the inclusion of Figure S2 did not affect the findings and conclusions of the G & D paper. Indeed, it is my understanding that the papers findings and conclusions would have been the same without Figure S2. Thus, Figure S2 was not material.

As stated earlier, it is not contested that Figure S2 was not material to the findings and conclusions of the G & D paper. Thus, one element that is missing regarding a misconduct





claim is intent. Indeed, Dr. L. Prakash and Dr. S. Prakash have about five decades of outstanding published research and are considered leaders in their field. Dr. Yoon has worked for them for about sixteen (16) years, with many highly regarded publications and no issues regarding his credibility or competence. Thus, there is no past pattern of misconduct by any of these three scientists. What these facts suggest is an honest mistake.

At the outset I must state that I am amazed and stupefied at how you as the SIO have handled this matter to date. As will be detailed below, from the very beginning of the process, you have failed to follow the procedures and rules set forth in UTMB's Policy and Procedure Manual on Integrity in Research ("PPMIR"). The PPMIR sets forth in simple language how you, as SIO, were to handle this matter. What makes this more perplexing is that you as SIO are charged with the knowledge of the procedures set forth in the PPMIR. Despite the clear requirement of you as SIO to know the procedures to handle a complaint about alleged misconduct, you failed to follow them not once, but now twice. Based on your failures and those of the Scientific Integrity Committee ("SIC"), Dr. Yoon, Dr. L. Prakash and S. Prakash have suffered greatly and continue to suffer.

Now as stated in their letter to you dated March 3, 2020, that was signed by Dr. L. Prakash. Dr. S. Prakash and Dr. Yoon, the PPMIR lays out specific steps that are to be followed by the SIO in conducting an inquiry that may lead to an investigation. As you are in possession of the March 3, 2020, letter, which I attach hereto as Exhibit A, I will not reiterate what has already been clearly laid out for you. However, I will state that before you were to start an investigation, you were to conduct an inquiry. At the end of the inquiry, you were to prepare a report as detailed very clearly in the PPMIR on page 10. These elements include (i) a summary of the inquiry process used; (ii) a list of the research records reviewed; (iii) the basis for recommending or not recommending that the allegations warrant an investigation; and (iv) any comments on the draft report by the Respondent or Complainant. Then when you created an inquiry report, you were to provide the findings of the inquiry to Drs. Prakash and Dr. Yoon and allow them to provide their written comments on the findings. Then and only then, you could provide the President of UTMB a copy of the inquiry report. But in doing so, you were also to provide to the President of UTMB the comments from Drs. Prakash and Dr. Yoon. As you are well aware, that is not what happened in the Fall of 2019.

The power to launch an investigation is vested solely in the President of UTMB. Only the President has the power to grant the right to start an investigation, *NOT* the SIO. Additionally, only if the President decides that an investigation is warranted can the SIO provide ORI with the President's written decision, as well as a copy of the inquiry report. Instead of following the clearly defined and simply stated PPMIR procedure, you took it upon yourself to launch in your words an "Investigation" of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. This started in September 2019, four months after the original complaint was filed. You then convened an SIC meeting in December 2019 to determine their guilt. Here again you failed to comply with UTMB's rules set forth in the PPMIR, which clearly state that the investigation committee is to





be formed only after the President of UTMB provides his written approval to start the investigation. Regarding the investigation committee, each of the individuals chosen was to be approved by Drs. Prakash and Dr. Yoon to ensure there was no conflict that would result in a prejudiced decision. Instead, you established an SIC without notifying Drs. Prakash and Dr. Yoon. You then compounded your mistake by failing to provide Drs. Prakash and Dr. Yoon an opportunity to review the SIC member list to provide their feedback and ensure there were no conflicts.

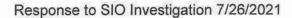
In November 2019, prior to the SIC meeting in December 2019, each of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon sent you a letter. (*see*, Exhibits B – D attached hereto). In these letters, you were provided a reasonable explanation how the error which led to the original Figure S2 occurred. Just as important, you were provided in great detail the measures undertaken by Dr. L. Prakash and Dr. Yoon to ensure a similar mistake *could not occur again*. It is clear by what happened next that you either did not read their letters or you ignored them. What is clear is that you never spoke with any of Drs. Prakash or Dr. Yoon about their letters that were sent to you, the SIO. I also reasonably believe that they were never provided to the President of UTMB or the SIC.

So, you continued your Investigation (your word at the time) and held the SIC meeting in December 2019 where a *judgment* was rendered. Dr. Yoon was to be fired. This was summarized in the "INVESTIGATION REPORT" of January 2, 2020, which is attached hereto as Exhibit E. It is clear from your INVESTIGATION REPORT that you did not read the letters from Drs. Prakash and Dr. Yoon. (*see*, Exhibits B – D). If you had, then the SIC would not have stated as a recommendation on page 3 of your INVESTIGATION REPORT – Recommendations of the SIC.

"that the Department Chair "evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis."

As stated, a process to ensure a similar mistake would not occur had already been implemented and was laid out for you *clearly* in the November 13, 2019, letter from Dr. Yoon. (*see*, Exhibit D). The fact that the SIC is not aware of the implementation of this procedure by Drs. Prakash's lab, clearly shows that you as SIO failed to provide them this critical information prior to the December 2019 SIC investigation meeting.

With the verdict from your investigation in hand, you pass on the verdict from your SIC to Drs. Prakash and Dr. Yoon on February 6, 2020. However, as you should know from the PPMIR, it is the President who decides on the appropriate action to be taken and only after the President determines that the findings substantiate the allegation of research misconduct. As is clear, you as SIO and the SIC had no legal basis to render such a verdict. In rendering a final judgment, you and the SIC *violated* the UTMB PPMIR and as a result you and the SIC caused and continue to cause great harm to Drs. Prakash and Dr. Yoon.





Now for reasons I do not understand, after Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon sent you their March 3, 2020, letter (*see*, Exhibit A) that laid out in detail all of your mistakes regarding the process set forth in the UTMB PPMIR and other issues with the verdict, you did not respond. Indeed, Drs. Prakash and Dr. Yoon did not hear from you again for almost a year when you sent an email to Dr. L. Prakash, as well as Valerie Rosemond and Carolee King, both of UTMB on March 23, 2021. (*see*, Exhibit F attached hereto). In your email, you stated that you had been asked by the Office of Research Integrity if the administrative actions, meaning the verdict rendered by the SIC in the INVESTIGATION REPORT, had been implemented. You then required that Dr. L. Prakash respond to you by March 29, 2021, with the answer.

On March 25, 2021, Drs. L. and S. Prakash responded. (*see*, Exhibit G). They pointed out to you that it was "perplexing" that you had ignored their March 3, 2020, letter, where you were informed in great detail that you *failed* to follow the UTMB PPMIR and *violated* their rights. If you, the SIO, had paid attention to their March 3, 2020, letter, at minimum, you ought to have realized right then that you and the SIC had made a grave error in having informed ORI. It was incumbent upon you at that time to have informed ORI that you had failed to follow the *required* steps of an inquiry under the UTMB PPMIR. You should have informed the ORI that you and the SIC failed to handle this matter properly. Then, you should have withdrawn the report from ORI and apologized to the ORI for your serious mistake. Of course, you and the SIC failed to undertake any of these required steps. As a result, the entire tainted process you pursued and the submission of the report to ORI were illegal, unwarranted, reckless, and extremely damaging to Dr. Yoon and Drs. Prakash.

As you should be well aware, your standard regarding how Dr. Yoon is to be treated for a single honest mistake must be applied to you as SIO and the SIC. Indeed, I would expect that you would agree that you as SIO should not receive preferential or better treatment than Dr. Yoon. Particularly, where you as SIO are charged with knowing the procedures and rules to be followed pursuant to the UTMB PPMIR. Indeed, your failure should be considered worse than Dr. Yoon's honest mistake. As under your own rules there are no do overs, I will continue to call the inquisition you launched and continue to prosecute an Investigation. I will also continue to call the January 2, 2020, verdict, the INVESTIGATION REPORT.

However, I do agree with that part of your statement that the SIC did not find any research misconduct by Dr. L. Prakash or Sr. S. Prakash. I also believe that based on this correct finding, that it was right to close the case against Drs. Prakash. I also understand that the NIH Office of Research Integrity ("ORI") came to the same conclusion in a letter sent to you on June 21, 2021, from Alexander Runko, Director, Division of Investigative Oversight, ORI. (see, Exhibit H attached hereto).

Response to SIO Investigation 7/26/2021



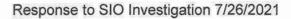
Next, I understand that you sent the INVESTIGATION REPORT to President Ben G. Raimer to request permission to start an investigation into Dr. Yoon. In doing this, you once again failed to allow Dr. Yoon to provide comments for President Raimer to assist in his decision. You also failed to interview Dr. Yoon or Drs. Prakash. So now for a second time, you failed to follow the procedures and rules set forth in the UTMB PPMIR. As you should be able to imagine, this is amazing and perplexing all in one. You were informed of your violation of UTMB's PPMIR almost a year and a half ago. You acknowledge in your discussions with the Director of ORI (your June 3, 2021, letter to the respondents) that you had made a mistake in labeling the SIC Report as an Investigation Report. It can only be assumed that this was based on the information provided by Drs. Prakash and Dr. Yoon. So, the SIO who wants Dr. Yoon fired for a single honest mistake continues to make mistake after mistake, even after being informed of her mistakes.

However, you received the result you wanted. You were able to intentionally mislead President Raimer and obtain his approval of an investigation into Dr. Yoon by gaming the system. You failed to inform President Raimer of your repeated failures to follow the rules as set forth in the UTMB PPMIR. The irony is that your compounded failures fail the standard of what one would hope for regarding a Scientific Integrity Officer of UTMB who is charged with upholding the school's standard of "Integrity."

With President Raimer's improperly attained approval in hand, you next requested that Dr. L. Prakash send you a list of Dr. Yoon's publications over the last five (5) years, which she did. And now, you are continuing your fishing expedition by asking for Drs. Prakash to send you the last five (5) years of their grant applications. To this, I say no on behalf of Drs. Prakash and Dr. Yoon. This inquisition needs to end and if there is an accounting to be had, it is of your incompetent and malevolent conduct and behavior as SIO in this affair. Indeed, it raises the serious question whether the SIO should be the one who is fired.

As stated previously, as SIO you are to follow very specific and simple rules and procedures on how to conduct an inquiry. Then, if reasonable and necessary, and following President Raimer's approval, you can conduct an investigation following the procedures set forth in UTMB's PMIR. You failed in this simple task, not once, but again after having your first failure pointed out to you. You continue to prosecute your inquisition, while failing to follow your own rules.

Further, throughout your inquisition, you have failed to provide an answer to a key component of the inquiry. Why would Dr. Yoon have intentionally created a false Figure S2 if it was not material. Particularly, when he has no history of falsifying data. You never obtained this answer because you never interviewed him on this specific point. If you had, you would have learned it was an honest mistake due to the pressure of working on multiple things at once on his computer as he stated in his November 13, 2019, letter to you. (*see*, Exhibit D). I would doubt that you or someone working in your lab has not or could not have made a similar mistake under the same circumstances.





Thus, based on the facts in this matter, it is clear that if there is to be an investigation, it should be of you and your conduct as SIO. You have tortured Drs. Prakash and particularly, Dr. Yoon for almost two (2) years with your inquisition for a simple non-material and honest mistake. You have caused each of them great physical, emotional and mental harm and whether you realize it, professional harm. You have done this despite Dr. Yoon letting you know of the great emotional, mental and physical toll your inquisition has taken on him personally. It is clear you do not care for their wellbeing.

Now your behavior and conduct as SIO raises serious legal and administrative issues. This includes your violation of Regents Rules of Conduct, Rule 30103. This rule explicitly states that any employee who, acting singly or in concert with others, obstructs, disrupts, or interferes with any research or other activity authorized to be held or conducted on campus or on property or in a building or facility owned or controlled by The University of Texas System or any of the institutions is subject to disciplinary action, including dismissal. It goes without saying that your willful inquisition, which has not followed the explicit rules and procedures set forth in the UTMB PPMIR has clearly disrupted the research and other activities of Dr. L. Prakash, Dr. S. Prakash, and particularly, Dr. Yoon.

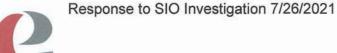
But your violations of the Regents Rules of Conduct do not stop there. Rule 30602 states that

"it is the policy of the University of Texas system or any of the institutions to encourage, fair, efficient, and equitable solutions for problems arising out of the employment relationship and to meet the requirements of State and Federal law."

It goes without saying that the inquisition that you have pursued against Drs. Prakash and Dr. Yoon has not been fair, efficient or resulted in an equitable solution. Instead, it has been wholly unfair, unreasonable, inefficient and just cruel. Particularly, when you consider the improper and illegal judgment of you as SIO and the SIC in the INVESTIGATION REPORT that Dr. Yoon be fired after 16 years of outstanding service for a non-material and honest mistake. In what universe can this be reasonably considered as an equitable solution. Your inquisition has caused Dr. Yoon great mental and physical anguish. It has resulted in serious emotional trauma.

Thus, it goes without saying that your actions over the last two (2) years as SIO of UTMB have resulted in cognizable and significant damage to each of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. So here is what we expect to happen to close this matter. You will provide a letter to Dr. Yoon stating that there is "no evidence" of misconduct by him. This will be shared with President Raimer, the ORI and each member of the SIC. Then you will close this matter.

Failure to take this reasonable step and end this charade will require Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon to consider the legal and administrative remedies available to them. As I am sure you are aware, these include obtaining legal redress for the cognizable harm they have suffered from the actions you as an individual have taken against them personally (clear federal civil rights violations), UTMB and the members of the SIC. It will also include filing a complaint



against you personally as SIO of UTMB with the General Counsel's Office of the University of Texas system for your actions and continued and knowing violation of the Regents Rules of Conduct and UTMB's PPMIR to the significant detriment of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. Other administrative remedies will also be considered.

This whole inquisition should have been terminated following your receipt of the letters from Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon in November 2019. By then the non-material and honest mistake had been corrected and procedures had already been implemented to ensure it would not happen again. But you decided to press your inquisition to the significant detriment of everyone, including UTMB and President Raimer. I expect that this will end now.

Sincerely,

Peter D. Weinstein, Ph.D., J.D.

Managing Partner



EXHIBIT A



6.104 Medical Research Building 301 University Boulevard Galveston, TX 77555-1061 O 409.747.8601

March 3, 2020

Dear Dr. Garg:

This letter is in response to the Investigation Reports you sent to each of us, the Respondents, Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.-H. Y) on Feb. 6, 2020 at 4:14 PM, in which you reproduce the allegations made by the complainant of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our Genes & Development publication, vol. 33, 282-287, 2019. These letters list the members of the UTMB standing SIC involved in both the Inquiry and Investigation and the Summary Statement and Recommendations of the SIC. Given serious issues with the process and significant concerns about the content of this investigation, we object to the recommendations proposed in it, namely dismissal of Dr. Jung-Hoon Yoon from UTMB.

Let me start with our serious concerns about the process. The guidelines of the Policy and Procedure Manual on Integrity in Research (PPMIR) are very clear on the steps that need to be taken in determining the merit of allegations of misconduct; however, as documented below, the proper procedures were not adhered to in this particular case.

Since the guidelines indicate that an inquiry report, which we have not seen and suspect does not exist, should have been sent to the President, we have copied him on this communication; and since we have discussed this matter with the Chair of our Department, we have copied Dr. Mariano Garcia-Blanco as well.

Page 7, section IV E of the PPMIR, states: "During the research misconduct proceeding, the SIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for by law and UTMB policies and procedures."

We did not receive any notices during the proceedings

We list below specific examples where proper procedures were not followed, along with our comments noted in bold:

- (1) Section VI A p.10 of the PPMIR details what the written Inquiry report should contain. Among other items, it should include a summary of the inquiry process used, a list of the research records reviewed, the basis of concluding whether or not an investigation is warranted, and any comments on the draft report by the Respondent or Complainant.
 - We were not provided with any such information and were given no opportunity to comment on the inquiry report.
- (2) Section VI B on p. 10 of the PPMIR states that the SIO shall provide a copy of the inquiry report to the President and to the respondent at the same time and that the respondent has 10 calendar days to send comments to the President regarding the contents of the inquiry report.
 - We were never given a copy of the inquiry report; therefore, we were not allowed the opportunity to send our comments to the President.

- (3) On p. 11 in section VI B of the PPMIR, it states that "The President will determine in writing whether an investigation is warranted."
 - The letters we received from you on Feb. 6, 2020 were entitled "INVESTIGATION REPORT" and state that the SIC members determined there was sufficient ground to proceed to the investigation step. This implies that several steps in the mandated process were not carried out according to the guidelines set forth in PPMIR.
- (4) Once the President has determined that an investigation is warranted, in section VII C, p. 12 of the PPMIR, it states that "The President, in consultation with the SIO and other institutional officials as appropriate, will appoint an investigation committee of at least 3 members..." Thus, the SIC and the Investigation Committee are NOT the same.
 - The bottom of page 1 of the letters we received from you lists the names, etc. of the UTMB SIC members involved in BOTH the inquiry AND the investigation.
- (5) On p. 12, in section VII C of the PPMIR, it states that "The President will notify the Respondent of the proposed committee membership to give the Respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest."
 - We never received any such notification. In fact, as noted above, the SIC committee performed both the inquiry and investigation reports whereas in the email of Sept. 17, 2019 at 1:25 PM, we were notified that it was an inquiry which you would like to complete in 60 days.
- (6) According to p. 13, section VII E of the PPMIR, the investigation committee and the SIO must interview each Respondent and Complainant.
 - None of us, the respondents, were interviewed by the Investigation Committee.
- (7) Section VIII. A on p. 14 provides a list of the elements that the written draft of the investigation report needs to include.
 - No details were provided in the investigation report.

The SIC's actions are even more troublesome in view of the fact that we had provided all the information we were asked for, as noted below.

Your email of Sept. 17, 2019 at 1:25 PM stated that "We would like to complete the inquiry in the next 60 days". In a later email that day (Sept. 17, 2019 at 3:28 PM) you wrote "Please provide us, in defense, documentation for the ability to detect endogenous level of Rev1, DNA Polymerase lota, DNA polymerase kappa in human or other cells used in the study, and original Western blots / images of the original blots, and documentation of the experiments." We, all 3 respondents: Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.H.-Y) provided you with extensive documentation of our ability to carry out these studies in our November 18, 2019 response to you. In addition, we provided the corrigendum for Supplemental Fig. 2 that has been published in Genes & Development. And in our letters (SP & LP), we pointed out the highly error-free track record of Dr. Yoon and we noted that the inclusion of Supplemental Fig. 2 had no bearing on the impact or conclusions of this study.

Between Sept 17 and Nov 18, before we sent you our letters of response, I (LP) communicated with you by telephone several times for advice on what information to include in our response. After

spending many hours examining the complainant's notebooks and comparing relevant pages to the Western Blots (WBs) he referenced, I found many discrepancies which led me to question the validity of his allegations. In the draft of my original response, I had included the following statement: "I want to point out that I spent a lot of time examining the notebooks of the individual making the complaint and I found several instances in which the points brought out by the complainant did not confirm the allegation." We (SP & I) accepted your suggestion to remove this statement because we were given the impression that it was not necessary – thinking that all you needed was the evidence you had asked for in your Sept. 17, 3:28 PM email. Therefore, we were shocked and traumatized to receive your email of February 6 with the attached Investigation Report letters, since we had not been made aware that the Inquiry Phase had progressed to the Investigation Phase.

We (LP & SP) have discussed this situation with our Chair, and respectfully request that the Guidelines of the PPMIR be followed and that the Inquiry and subsequent steps be re-initiated from the beginning. Importantly, I (LP) have uncovered that the majority of the complainant's allegations cannot be substantiated, and it is only if the Inquiry is followed in the proper order that we can discuss these issues with the SIC inquiry committee, and with the Investigation Committee, should it proceed to that stage.

The precipitous action of the SIC and its recommendations, especially the extreme one that Dr. Yoon be terminated from UTMB, without consideration of his excellent track record, path breaking publications, and his devotion to science (for a detailed explanation see our letters that were included in our Nov. 18, 2019 email to you and are attached here) have been extremely devastating to all the respondents. We also feel that no consideration was given to the circumstances under which this error occurred, for which Dr. Yoon has been extremely remorseful, and the steps we have undertaken to avoid such errors in the future (see Section §93.408 Mitigating and aggravating factors in HHS administrative actions, p. 648 of Public Health Service: Policy on Scientific misconduct 42 CFR Part 93).

Content of Allegations

In this communication, we have not addressed in detail the content of the allegations. We will comment on them at the appropriate stage and will do so in great detail.

Thank you very much.

Sincerely,

Louise Prakash

Louise Prakash

Satyr Prakash

Satyr Prakash

Jung-Hoon Yoon



Response to SIO Investigation 7/26/2021

EXHIBIT B



Subject: Genes & Development paper

November 5, 2019

Dear Committee:

At the outset, I categorically state that I had no knowledge of any issues with the western blots (WBs) shown in Supplemental Figure 2 and I was in no way involved in any of the aspects of constructing this figure.

I have worked closely with Hoon since he joined our group in March 2005. In my long academic career, he is one of the very best colleagues that I have worked with. Hoon has high ethical standards; he cares deeply about discovering the truth and reporting the scientific facts, and his impeccable and impressive first author contributions with us over the past 10 years attest to this fact.

I have thought long and hard about how Hoon, who is such a diligent and highly conscientious individual who repeats experiments too many times to assure the accuracy of his data and conclusions, could end up being responsible for mixing up the information assembled in Supplemental Figure 2. Knowing Hoon as a person and as a scientist as well as I do, knowing the difficult circumstances in which this work was being put together, and the fact that he shares all the important aspects of a project with me, regardless of how negatively that may impact the outcome of the study or its publication, and irrespective of the time he has spent on it, I can affirmatively say that there is absolutely no way that this highly distressing episode occurred because it was in any way intentional.

In the original version of the paper submitted to G&D, we had not included Supplemental Figure 2 because the observation that depletions of respective DNA Pols reduce the frequency of translesion synthesis (TLS) opposite1,N6-ethenodeoxyadenosine (ϵ dA) had provided strong genetic evidence for the effectiveness of siRNA depletions and also because we had published such evidence before. Moreover, since in the revised version, we had included the evidence generated in Rev1- $^{1/2}$ and Pol $^{1/2}$ mouse embryonic fibroblasts (MEFs) that a reviewer had asked for, it was not necessary to include a western blot (WB) figure of siRNA depletions,. Even then I decided to include a WB figure of siRNA depletions in the revised version and asked Hoon for such a figure. I believe that this unnecessary and undue burden I put upon Hoon to assemble such a figure in a short time led to errors in compilation of this figure.

Over the years, Hoon has been working almost single-handedly on a number of novel and path-breaking projects and he has been under pressures which he puts upon himself and the pressures that I put upon him. I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion. Clearly, he did not realize the degree of mental exhaustion or the mistakes he was making when he put the figure together. It is impossible for me to see that Hoon, who cares so deeply about the validity of his results and conclusions, would knowingly misrepresent a figure which has little bearing, if any, on the data shown in the paper or on the conclusions drawn. A person with intent to falsify or misrepresent data would do so for aspects which elevate the impact of the study and not something as marginal as this figure.

In reviewing all the past contributions of Hoon with us, I have become deeply aware of the immense amount of information he puts together in preparation for each paper, and of how error-free and meticulous each of his publications is. Nevertheless, to avoid the possibility of any errors in the future, I will help Hoon in verifying the accuracy of each of the items that are included in the paper. I will also make sure that Hoon is not working on a number of different projects at the same time.

Hoon has been traumatized by the fact that he is responsible for this mishap in the figure. He is a highly devoted scientist who cares deeply about the accuracy and biological relevance of his findings and over the years with us, he has been responsible for a number of pioneering studies published in a number of leading journals, including Cell, Genes & Development, PNAS, and others Moreover, Hoon has been working assiduously on a number of other important projects. I strongly believe that publication of these studies will be highly impactful and paradigm shifting for a number of DNA repair genes which play highly effective roles in protection from breast and ovarian cancers and from leukemias.

Sincerely yours,

Satya Prakash, Ph.D.

Satya Prakash

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology 6.104B Medical Research Building

Telephone: 409-747-8602 e-mail: saprakas@utmb.edu Response to SIO Investigation 7/26/2021



EXHIBIT C



Subject: Genes & Development paper

November 13, 2019

Dear Committee,

I wish to state at the outset that I was not involved in any way in assembling the data for the gels presented in Supplementary Figure 2. My role was to combine the Supplementary Figure files given to me into one pdf file for submission to the journal, along with the text and text figures.

Both Satya and I were shocked when we learned about the allegation against Dr. Jung-Hoon Yoon, the first author of a manuscript published in Genes & Development in March of this year. It is important to understand the kind of person that Hoon is because then it becomes totally incomprehensible that Hoon could have knowingly and intentionally misrepresented the data in Supplementary Figure 2. He has been with us for the past 14 years, and during that time, I have had ample opportunity to observe the way he conducts himself in his research and how meticulous he is with his data. He is extremely honest, forthright, conscientious, and a most trustworthy, reliable, hardworking, and responsible individual. He always repeats his experiments numerous times to be as sure as one can ever be in science that the data are reproducible and that the conclusions are warranted. The quality and quantity of work that has gone into each of his publications shows that he has accomplished a phenomenal amount of work. He has single-handedly been doing the work that in other labs would be handled by a number of individuals. In fact, one of the reviewers of the recent Cell paper on which Hoon is first author said "This is a monumental work that addresses a key problem in skin cancer and elucidates the roles of Pol0 and other TLS polymerases." (Underline mine). And another reviewer wrote "These data provide unambiguous evidence of skin cancer arising in the absence of UV induced mutations. This is a paradigm-shifting finding as it questions the dogma that UV induced mutations cause skin cancer". In this paper as well as in all his other papers, Hoon has been the prime mover - being responsible for the major aspects of the study.

After going over the details with Hoon it has become clear to me that Hoon was working under tremendous pressure at the time he prepared this figure. He was asked by Satya to provide a figure of western blots showing siRNA knockdowns of the various TLS polymerases used in the study, Hoon made errors because during compilation of a number of western blots, he had many gel images open at the same time, and he picked the wrong images. When Hoon realized what he had done, he was completely devastated. He blamed himself endlessly, and felt strongly that he has brought shame on himself as well as on all others associated with him. It took several days for him to recover sufficiently to be able to address with us the details of how this might have come about. He made a genuine mistake, and I cannot over-emphasize how truly remorseful he has been. This is all because he takes his scientific work very seriously.

I have gone over various ways to reduce the probability of errors arising in the future regarding confusion in identifying western blots or similar types of data. We both agree that annotating each blot with a western blot marker pen such that the date and samples are clearly indicated will be most useful to achieve this end. In addition, applying the same code to the original file

name created by the ImageQuant instrument and to the corresponding blot should avoid any ambiguity as to the identity of the blot. He will also keep a detailed record in a lab notebook where the code name will include an illustrator file of the blot and a legend indicating what is in each lane and the relevant experimental conditions used. From now on, I will carefully go over with Hoon's record keeping in this regard and I am confident that this strategy will serve to avoid mistakes in the future.

We have compiled a new Supplementary Figure 2 and have sent this figure to Genes & Development to be published as a Corrigendum. I have been corresponding with Dr. Laureen Connell, Senior Editor, Genes & Development, regarding the corrigendum and there do not seem to be any issues with replacing the figure. The emails from Dr. Connell are included with the materials provided to the committee.

Thank you for giving us the opportunity to explain the circumstances that led to mistakes in the compilation.

Sincerely yours,

Louise Prakash, Ph.D.

Laure Propost

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology

6.104A Medical Research Building

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT D



November 13, 2019

Letter of Explanations to Scientific Integrity Committee

In going over Supplementary Figure S2, I have realized that I failed to keep a record of how I had compiled this figure and it has become clear to me that I made errors in assembling this figure. I am always very concerned about the accuracy and repeatability of my data and I have been extremely upset about not being careful in assembling this figure. I want to emphasize that all these mistakes are unintentional errors and I wish to explain the circumstances under which this figure was made.

I joined the Prakash lab in 2005 with a specific purpose of studying translesion synthesis (TLS) mechanisms in human cells. For this purpose, I designed a novel duplex plasmid system in which replication through a site-specific DNA lesion present on the leading or the lagging DNA strand could be analyzed methodically. For determining the contribution of various TLS polymerases (Pols), I began using siRNA depletion method as this approach avoids the complications of genetic suppression or other genetic artifacts that accompany null mutations. After over two years of effort, I established the plasmid system and optimized the efficient siRNA depletion conditions for a number of TLS Pols in human and mouse cell lines. To confirm the efficient siRNA depletion of TLS Pols in mammalian cells, I used western blot analysis and if necessary, RT-PCR. The establishment of these approaches has allowed me to systematically analyze the genetic control of TLS opposite different types of DNA lesions in human cells and these studies have been published in prestigious scientific journals.

When I prepared the Figure S2 for the Genes & Development paper, I was working under tremendous pressure of time and of having to deal with a number of different ongoing studies. Moreover, in the last year I had taken over the work of post-docs who had left the laboratory. At the same time, I was handling a rather complex paper for Cell, and when Satya wanted me to provide a new figure for siRNA depletions, because of the concern for the revision deadline, I rushed to finish the figure. I opened many files of western blot images on the computer screen and because of lack of attention and confusion, I mixed up the files and didn't double check the final figure before submission. I do realize that there is no excuse for my making these mistakes; from now on, I will be much more careful so that such mistakes never happen again.

To avoid such errors from occurring in the future, I have discussed a strategy with Louise which I plan to follow. Our laboratory uses the ImageQuant LAS4000 camera system for obtaining digital images of our western blots of other samples. The digital images are produced by exposing the blot to chemiluminescence and the system automatically names the file with the date it is created. From now on, for each file genrated by the ImageQuant, I will add a code name to each corresponding blot using a western blot marker pen so that there will be no ambiguity as to the identity of the samples in a particular blot. In addition to annotating each blot with the date and sample name, I will keep a detailed record of each blot in a notebook where every lane of the particular blot will be clearly labeled as to what sample is in each lane, what antibody was used, and any other pertinent experimental details. Blots will not be copied into adobe illustrator until they have been clearly marked. We expect that this procedure will substantially reduce the probability of error. In addition, I will consult with Louise and show her my annotation system so that there will be no confusion as to what each blot represents.

Thank you very much for considering my explanation of the circumstances that led to this unfortunate, and entirely unintentional, incident for which I take full responsibility.

Sincerely yours,

Jung-Hoon Yoon, PhD

Research Scientist

Biochemistry and Molecular Biology

6.108 Medical Research Building

Telephone: 409-747-8604; e-mail: juyoon@utmb.edu

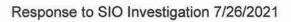




EXHIBIT E

University of Texas, Medical Branch in Galveston ("UTMB")

Confidential Sensitive

Allegations of Research Misconduct Respondent: Prakash Satya, PhD

Date of SIC Meeting: December 19, 2019

Report Date: January 2, 2020

1. INVESTIGATION REPORT

1.a. Background and summary of Inquiry

In a message dated May 5, 2019, allegations of research misconduct were raised by a complainant. The allegations stated possible research misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019).

Panel A - top left: blot for TLS Pol in NC/Poln samples is from another blot for a different protein.

Panel A - middle left: Polφ data is from another blot for a different protein in different cells, Rev1 blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Poli data are from a blot for another protein.

Panel B- Western blot for Poli and tubulin for NC/Polo samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data. This manuscript cites support from US PHS funds, specifically NIH grants ES022948 and GM126087 (PI: Prakash).

Though the complainant identified Yoon, Jung-Hoon, PhD, Research Scientist in the Department of Biochemistry and Molecular Biology (BMB) as respondent. Dr. Yoon was identified to directly report to Dr. S Prakash. Thus, Dr. S Prakash was also identified as respondent.

Dr. NJ Garg Scientific Integrity Officer (UTMB) met the complainant in May 2019 and received the material justifying the allegation. The material received from complainant is attached as **Appendix 1**.

Dr. Garg (and Ms. Bricker) met Dr. Yoon, Dr. S. Prakash and Dr. L Prakash (identified as respondents) on Sept 16 and Sept 17 to present the allegation. Notebooks and computer hard drive were sequestered on September 16. The Scientific Integrity Committee members determined there is sufficient ground to perform investigation.

The Investigation

1.b. Names, titles and CVs for UTMB SIC members involved in Inquiry and Investigation.

The members of the UTMB standing SIC are listed below. The biosketches of the members are available on request.

Dr. Nisha J Garg, PhD MBA (Professor, Microbiology & Immunology, School of Medicine (SOM) and Scientific Integrity Officer)

Dr. Giulio Tagliatela, PhD (Professor, Neuroscience, SOM and Chair, SIC)

Dr. David H Walker, PhD (Professor, Pathology, SOM)

Dr. Lorraine Evangelista, PhD (Professor, School of Nursing)

Dr. Blake Rasmussen, PhD (Professor, Nutrition and metabolism, School of Health Professions)

Dr. Rebeca Wong, PhD (Professor, Preventive Medicine and Community Health, SOM)

Dr. B Monte Pettitt (Professor, Biochemistry & Molecular Biology, SOM)

Dr. V Suzanne Klimberg (Professor, Surgery, SOM)

Ms. Carolee A King (JD Senior Vice President & General Counsel, ex officio member)

Ms. Kimblyn Raschke / Ms. Nancy Bricker (Administrative support, ex officio)

1.c. Names and titles of all respondents:

Respondent S Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent L Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent Yoon, Research Scientist, Biochemistry and Molecular Biology, UTMB

1.d. Attorneys if relevant: None

1.e. PHS support/ORI jurisdiction.

The following grants funded by NIH were cited in the publication:

<u>Paper</u> <u>Grants</u>

Paper: Genes & Development 33:282-287 (2019) ES022948 and GM126087

2. Investigation process:

Dr. Garg and Ms. Bricker met the respondents on Sept 6-7, 2019 to present the allegation and sequester the relevant notebooks and hard drive.

The respondent L Prakash kept contact with Dr. Garg through emails and phone calls and provided detailed response on November 18, 2019. The statements received from all respondents are attached as **Appendix 2**. Respondent has also provided new data (**Appendix 3**) and communications with the journal (**Appendix 4**).

The collected information and data were sent to the members of the SIC investigation committee electronically on 11/19/2019. Members discussed the case electronically and formally met on December 19, 2019.

The presented report was approved by SIC members by January 25, 2020 and the legal counsel on February 6, 2020.

3. Summary:

Dr. S Prakash (respondent) states, "I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion". Dr. S Prakash (respondent) maintains that it was an honest error of Dr. Yoon.

All respondents could not identify the original gels that were used to submit Figure S2. Lacking that, all experiments/WB for Figure S2 were repeated, and new data were utilized to assemble new Figure S2 (attached as Appendix 3). The newly generated Figure S2 was sent to the G&D journal (Appendix 4). The journal accepted to publish revised version of the Figure S2 as corrigendum.

Scientific Integrity Committee: The person who ran Western blots in the lab has moved to another location. His folders were sequestered and found to be appropriately labeled with all details and needed information. However, the data presented in S2 Figure were found to be cut from images that belonged to data collected with other antibodies. Dr. Yoon was directly involved in assembling the data for publication and he accepted the responsibility for mis-presentation of data. Dr. S Prakash was not identified to have direct knowledge of mis-presentation of data.

SIC members unanimously concluded that falsification and fabrication of data occurred. SIC members considered that a lack of supervision and over-confidence in the capabilities of Dr. Yoon likely resulted in mis-presentation of data. However, SIC members concurred that there is no evidence that suggest that Dr. Prakash had direct knowledge of mis-presentation of data and he was likely not involved in falsification and fabrication of the data presented in Figure S2.

- 4. Recommendations of the SIC: Members of the SIC recommended the following:
 - 1. SIC members request the Chair of the Department to evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis. It will be essential that PI is aware of and has confirmed the accuracy of all raw data to be used for future publications.
 - 2. Notification to the Office of Research Integrity and Federal Funding Agency.
- 5. Notice to the respondent of the institutional decision and administrative action. Pending

Submitted by:

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston

O: 409-747-6865, E: nigarg@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT F

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 248 of 514

From: Garg, Nisha <nigarg@utmb.edu> Sent: Tuesday, March 23, 2021 4:26 PM

To: Prakash, Louise <loprakas@UTMB.EDU>; Prakash, Satya <saprakas@UTMB.EDU>

Cc: Rosemond, Valerie S. <vsrosemo@UTMB.EDU>; King, Carolee A. (Legal) <caaking@UTMB.EDU>

Subject: G&D paper

Hello Louise and Satya. I have been asked by the office of research integrity to address if the administrative actions recommended in Scientific Integrity Committee report are implemented. For this purpose, I request you to let me know the current employment status of Dr. Hoon and the lab procedures/protocols that are implemented/followed to ensure proper recording of the data and gel images in the lab.

Please send your response by Monday March 29th at the latest. Thank you

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer Professor, Microbiology & Immunology University of TX Medical Branch at Galveston O: 409-747-6865; E: nigarg@utmb.edu



Response to SIO Investigation 7/26/2021

EXHIBIT G

Prakash, Louise

From:

Prakash, Louise

Sent:

Thursday, March 25, 2021 2:27 PM

To:

Garg, Nisha

Cc:

Raimer, Ben G.; Garcia-Blanco, Mariano A.; Rosemond, Valerie S.; King, Carolee A. (Legal)

Subject:

RE: G&D paper

Attachments:

Response to Investigation Report letters

Importance:

High

Dear Nisha,

We find your communication of March 23, 2021 (4:26 PM) perplexing because we had sent you an email letter over one year ago, on March 3, 2020, documenting in great detail our serious concerns regarding the allegation of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our *Genes & Development* publication (2019, vol. 33, 282-287). In addition to sending that email and the attached materials to you, we had copied President Ben Raimer and our Chair, Dr. Mariano Garcia-Blanco. As you will note in that email (which is attached here), we expressed our concerns in detail and cited numerous examples of how procedures described in the <u>Policy and Procedure Manual on Integrity in Research (PPMIR)</u> of the University of Texas Medical Branch at Galveston had not been followed. Since we did not hear from you, we assumed that the matter had been closed. We have discussed this matter again with Dr. Garcia-Blanco and he shares our concerns.

Dr. Yoon's employment status at UTMB remains the same and he continues to make seminal contributions to translesion DNA synthesis mechanisms. Also, we stress that for each experiment we have been following very methodical and stringent procedures to ensure proper recording of the data and gel images.

Sincerely,

Louise Prakash, Ph.D.

Professor, Department of Biochemistry and Molecular Biology
I.H. Kempner Professor in Human Genetics

loprakas@utmb.edu

Satya Prakash, PhD.

Professor, Department of Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences saprakas@utmb.edu Response to SIO Investigation 7/26/2021



EXHIBIT H

DEPARTMENT OF HEALTH & HUMAN SERVICES



Office of the Assistant Secretary for Health Office of Research Integrity 1101 Wootton Parkway, Suite 240 Rockville, MD, 20852

Phone 240-453-8800

FAX: 301-594-0043 Email: alexander runko a hhs gov Web: https ori dhhs gov

CONFIDENTIAL/SENSITIVE

June 21, 2021

Nisha Jain Garg, Ph.D., MBA Scientific Integrity Officer Professor, Microbiology & Immunology University of Texas Medical Branch 301 University Blvd. Galveston, TX 77555-0342

TRANSMITTED VIA EMAIL TO: nigarg@utmb.edu

RE: ORI 2021-18 (DIO 7323)

Dear Dr. Garg:

The Division of Investigative Oversight (DIO), Office of Research Integrity (ORI), has reviewed the report of the inquiry conducted by the University of Texas Medical Branch in Galveston (UTMB) into allegations of possible research misconduct against Louise Prakash, Ph.D., Professor, Department of Biochemistry and Molecular Biology, UTMB. Dr. Prakash allegedly falsified and/or fabricated data in a supplementary figure in one (1) published paper. The questioned paper cited support from U.S. Public Health Service (PHS) funds, specifically National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES022948 and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM126087.

DIO concurs with UTMB's determination that there is insufficient evidence against Dr. Louise Prakash to warrant proceeding to an investigation. Therefore, DIO has administratively closed this case without further action.

Consistent with Federal law and ORI policy, research misconduct proceedings that result in no PHS finding of misconduct remain confidential for ORI. We ask that you respect this policy. We appreciate your reporting to DIO under 42 C.F.R. § 93.309.

¹Yoon J-H, Johnson RE, Prakash L, Prakash S, DNA polymerase θ accomplishes translesion synthesis opposite 1, N⁶ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes Dev. 2019 Mar 1;33(5-6):282-87.

CONFIDENTIAL/SENSITIVE

ORI 2021-18 (DIO 7323)

Page 2

If you have any questions about this matter, please contact me at alexander.runko@hhs.gov or 240-453-8800.

Sincerely,

Alexander P.

Digitally signed by Alexander P.

Runko -S

Runko -S

Date: 2021.06.22 16:34:42 -04'00'

Alexander Runko, Ph.D.

Director

Division of Investigative Oversight Office of Research Integrity

From: Runko, Alexander (HHS/OASH)

To: <u>Peter Weinstein</u>

Subject: RE: Follow up on UTMB matter ORI ORI 2021-16

Date: Monday, September 19, 2022 3:52:19 PM

Attachments: image001.png

image003.pnq image004.jpq image005.jpq image006.jpq image007.png

Dear Peter,

Thanks for your message. This remains an open matter and no action has been taken by ORI. We will let you know if we have any questions or need clarification about the information that you have provided.

Best, Alex

Alexander Runko, Ph.D.

Director, Division of Investigative Oversight
Office of Research Integrity
U.S. Department of Health and Human Services

ori.hhs.gov/		
	?	

From: Peter Weinstein < Peter. Weinstein@entralta.com >

Sent: Sunday, September 18, 2022 12:49 PM

To: Peter Weinstein < Peter. Weinstein@entralta.com>; Runko, Alexander (HHS/OASH)

<Alexander.Runko@hhs.gov>

Subject: Follow up on UTMB matter ORI ORI 2021-16

Dear Dr. Runko,

I am following up to see if there has been any action taken on the complaint filed against Dr. Garg. It has been almost a year since the complaint was filed and we have not heard anything or received any updates. I would greatly appreciate if you could provide an update and let me know if you need anything else from us.

Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D. Managing Partner



Entralta P.L.L.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive
Suite 212, PMB 511
Georgetown, TX 78633
P 805-444-7865
F 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

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From: Runko, Alexander (HHS/OASH) < <u>Alexander.Runko@hhs.gov</u>>

Sent: Friday, October 29, 2021 1:13 PM

To: Peter Weinstein < peter.weinstein@entralta.com >

Subject: RE: Information and Complaint Regarding Dr. Nisha Garg, former SIO of UTMB

Dear Mr. Weinstein,

I am acknowledging receipt of your email with your letter and the attachments. ORI will review the material concerning this matter and follow-up if we have any questions or requests for additional information. For your reference, ORI has assigned this UTMB matter as ORI 2021-16 in our case records. Please use this case number in all future correspondence about this case. If you have any questions, please do not hesitate to contact me.

Best, Alex

Alexander Runko, Ph.D.

Director, Division of Investigative Oversight Office of Research Integrity

Email: alexander.runko@hhs.gov

Office: (240) 453-8800 Desk: (240) 453-6018 https://ori.hhs.gov/



From: Peter Weinstein < <u>peter.weinstein@entralta.com</u>>

Sent: Monday, October 25, 2021 9:39 PM

To: Runko, Alexander (HHS/OASH) < <u>Alexander.Runko@hhs.gov</u>>

Cc: Peter Weinstein < <u>peter.weinstein@entralta.com</u>>

Subject: Information and Complaint Regarding Dr. Nisha Garg, former SIO of UTMB

Dear Dr. Runko,

I am sure that the letter with attachments that I am sending to you may be considered a little odd, but the situation at UTMB calls for such measures. I am aware that you know of at least part of the situation regarding Drs. Louise and Satya Prakash and Dr. Jung-Hoon Yoon at UTMB. The short is that Dr. Garg repeatedly and willfully violated UTMB's procedures and rules, the University of Texas Regents Rules of Conduct and likely most relevant to the NIH ORI, multiple sections of CFR 42, part 93 in her role as SIO during her conduct of an alleged investigation that has been more inquisition than an act to find the truth of the situation.

In saying that, I would greatly appreciate if you would take the time to read the attached letter and attachments. They provide a comprehensive summary of Dr. Garg's malfeasance over the last two years. It is noteworthy that UTMB has removed Dr. Garg from her role as SIO recently, which we believe is due to her bad acts and malfeasance regarding her investigations of Drs. Prakash and Dr. Yoon.

Finally, as you will gather from my letter and other attachments, Dr. Louise Prakash, Dr. Satya Prakash and Dr. Yoon reasonably believe that Dr. Garg's bad acts and malfeasance rise to a level that the NIH ORI should undertake an investigation of Dr. Garg and her actions during her over two years investigation of Drs. Prakash and Dr. Yoon.

Please confirm receipt of this email land the attachment and feel free to contact me with any questions or if you would like to speak with Dr. Louise Prakash, Dr. Satya Prakash and Dr. Yoon.

Best Regards,

Peter D. Weinstein, Ph.D., J.D. Managing Partner

Entralta P.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive
Suite 212, PMB 511
Georgetown, TX 78633
P 805-444-7865
F 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

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November 1, 2021

Dr. Ben Raimer President, UTMB Suite 6.100 Administration Bldg. 301 University Blvd. Galveston, Texas 77555-0129 Tel: (409) 772-1902

Email: bgraimer@utmb.edu

Dear President Raimer,

We are sending you this letter to file a formal complaint against Dr. Nisha Garg, the former Scientific Integrity Officer ("SIO") of the University of Texas Medical Branch at Galveston ("UTMB"). We are filing this complaint with you as it is our understanding that Dr. Garg in her role as SIO of UTMB reported to you personally. This complaint is being filed based on our allegations that Dr. Garg has violated multiple rules of the University of Texas Regents Rules of Conduct. In particular, this formal complaint is being filed pursuant to Dr. Garg's violation of Rule 30103 and Rule 30602. This complaint should not be a surprise as Dr. Garg was made aware of her violations of these two Rules in a letter from our counsel to her dated July 26, 2021, to which you were cc'd by email.

Starting with Rule 30103: Standards of Conduct, Section 2 of this Rule states that:

"Sec. 2 Disruption of Activities. Any employee who, acting singly or in concert with others, obstructs, disrupts, or interferes with any teaching, educational, research, administrative, disciplinary, public service, or other activity, meeting, or event authorized to be held or conducted on campus or on property or in a building or facility owned or controlled by The University of Texas System or any of the institutions is subject to disciplinary action, including dismissal."

It goes without saying that Dr. Garg's actions starting in September 2019 and continuing until her termination as SIO on October 15, 2021 clearly violated this section of the Regents Code of Conduct. Instead of reiterating all of Dr. Garg's actions that violated Rule 30103 in her repeated mistakes and mishandling of her alleged inquiry and investigation into an honest mistake in a supplementary figure in a paper, I am attaching several letters that go into great detail and include attachments that set forth all of Dr. Garg's wrongful acts. These are the letter our attorney sent to her on July 26, 2021 with its attachments (attached as Exhibit I), a letter our attorney sent to Daniel Sharphorn, the General Counsel of the University of Texas (attached as Exhibit II) and a letter our attorney recently sent to the NIH Office of Research Integrity detailing Dr. Garg's malevolent and malicious acts (attached as Exhibit III). It is clear from these letters and your own personal knowledge that Dr. Garg failed to follow UTMB's Policy and

Procedure Manual on Integrity in Research ("PPMIR") and violated multiple sections of federal law. In particular, sections of CFR 42, part 93.

It is incontrovertible that Dr. Garg's actions in carrying out her inquiries and investigations starting in May 2019 and continuing through October 15, 2021, disrupted and interfered with each of our ability to conduct our research and other obligations as employees of UTMB. Dr. Garg's actions have made the last over two years exceedingly and unreasonably hard on all of us. We have all suffered great emotional, mental and physical stress, particularly, Dr. Yoon whom Dr. Garg called to be fired almost two years ago. We all have also suffered great embarrassment through Dr. Garg's misinformation campaign to the NIH ORI. Dr. Garg's actions have interfered with our ability to conduct our research, and they have affected our health and overall wellbeing. No one should have to go through what Dr. Garg has put the three of us through. Dr. Garg's over two years of inquiries and investigations, which she continued to handle improperly after having her repeated mistakes pointed out to her, clearly constitute a violation of Rule 30103 of the Regents Code of Conduct.

Next, Dr. Garg has also violated Regents Rule of Conduct 30602. Rule 30602 states that:

"it is the policy of the University of Texas system or any of the institutions to encourage, fair, efficient, and equitable solutions for problems arising out of the employment relationship and to meet the requirements of State and Federal law."

Dr. Garg's inquiries and investigations that began in May 2019 were neither fair, efficient nor equitable. Moreover, her solution at the outset to fire Dr. Yoon was neither fair nor equitable for what was clearly an honest mistake. Further, Dr. Garg in her mishandling of her inquiries and investigations violated 42 CFR §93.301(b)(2), 42 CFR §93.302(a)(2)(i – ii), 42 CFR §93.304(b, e and f), 42 CFR §93.305(b), 42 CFR §93.307(a)(1 – 3), 42 CFR §93.307(d)(1 – 2), and 42 CFR §93.307(e – g). The implication of this is significant as Dr. Garg was the SIO representing UTMB when she broke these federal laws, which can be reasonably construed to mean that UTMB and the University of Texas System have broken these federal laws. What makes it worse is that several of these sections were violated by Dr. Garg not once, but multiple times as she attempted to muddle through her inquiries and investigations three times. As we noted above, her violations of the Code of Federal Regulations have been brought to the attention of the National Institutes of Health ("NIH") Office of Research Integrity ("ORI").

Dr. Garg's actions in violating Rules 30103 and 30602 are a stain on UTMB and the University of Texas system and an investigation needs to be immediately launched with regard to these violations. Not only does the investigation have to delve into Dr. Garg's actions and determine what consequences should flow from her violations of these two Regent Rules of Conduct, but we would also ask that the investigation determine why and how whoever was to oversee Dr. Garg's actions failed to maintain institutional control with the results that she was allowed to continue with her malevolent actions and violations of the PPMIR and CFR 42, part 93.

In the end, the sad part of all of this is that none of it had to happen. This whole mess has been over an honest mistake that was rectified, including immediately changing laboratory procedures to ensure this mistake could not happen again. In fact, the journal Genes and Development merely published a corrigendum when the mistake was brought to their attention. It should have ended there.

So with this letter we are formally requesting an investigation into Dr. Garg for violation of the Regent Rules of Conduct 30103 and 30602 and for the investigation to examine how Dr. Garg could continue over more than two years without proper institutional control. We appreciate your time in reviewing this letter and the attachments hereto. If you have any questions, you should feel free to reach out to us.

Best regards,

Louise Prakash, PhD

Professor

Biochemistry and Molecular Biology

Louise Prapash

Satya Prakash, PhD

Satya Pralase

Professor

Biochemistry and Molecular Biology

Jung-Hoon Yoon, PhD

Je my prong own

Research Scientist III

Biochemistry and Molecular Biology

Enclosures

Exhibit I



Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D. Phone: 805-444-7865 Fax: 805-322-4469

July 26, 2021

Nisha Jain Garg, Ph.D., MBA Scientific Integrity Officer Professor, Microbiology and Immunology University of Texas Medical Branch, Galveston O: 409-7476865

E: nigarg@utmb.edu

RE: Response to Investigation of Drs. Louise, Satya Prakash and Dr. Jung-Hoon Yoon

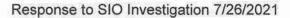
Dear Dr. Garg,

I have been engaged by Drs. Louise and Satya Prakash (individually, "Dr. L. Prakash" and "Dr. S. Prakash" and collectively, the "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") to represent them regarding the investigation undertaken by you on behalf of the University of Texas Medical Branch, Galveston ("UTMB") as UTMB's Scientific Integrity Officer ("SIO") regarding the genesis of Supplementary Figure 2 ("Figure S2") that was published in Genes & Development 33:282 – 287 (2019) (the "G & D paper").

I understand that your investigation started based on a complaint filed by a former member of the Prakash lab group who worked with Drs. Prakash. This complaint was filed with you as SIO in May 2019 and claimed that Figure S2 did not include the right gels.

I also understand that upon learning of the mistake regarding Figure S2 on or about September 2019, Dr. Yoon reran the experiments and then took the new gels to create a substitute Figure S2. This substitute Figure S2 was sent to G & D to be published as a Corrigendum. I understand that the substitute Figure S2 was accepted and published as a Corrigendum by G & D. I understand that the inclusion of Figure S2 did not affect the findings and conclusions of the G & D paper. Indeed, it is my understanding that the papers findings and conclusions would have been the same without Figure S2. Thus, Figure S2 was not material.

As stated earlier, it is not contested that Figure S2 was not material to the findings and conclusions of the G & D paper. Thus, one element that is missing regarding a misconduct



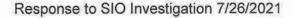


claim is intent. Indeed, Dr. L. Prakash and Dr. S. Prakash have about five decades of outstanding published research and are considered leaders in their field. Dr. Yoon has worked for them for about sixteen (16) years, with many highly regarded publications and no issues regarding his credibility or competence. Thus, there is no past pattern of misconduct by any of these three scientists. What these facts suggest is an honest mistake.

At the outset I must state that I am amazed and stupefied at how you as the SIO have handled this matter to date. As will be detailed below, from the very beginning of the process, you have failed to follow the procedures and rules set forth in UTMB's Policy and Procedure Manual on Integrity in Research ("PPMIR"). The PPMIR sets forth in simple language how you, as SIO, were to handle this matter. What makes this more perplexing is that you as SIO are charged with the knowledge of the procedures set forth in the PPMIR. Despite the clear requirement of you as SIO to know the procedures to handle a complaint about alleged misconduct, you failed to follow them not once, but now twice. Based on your failures and those of the Scientific Integrity Committee ("SIC"), Dr. Yoon, Dr. L. Prakash and S. Prakash have suffered greatly and continue to suffer.

Now as stated in their letter to you dated March 3, 2020, that was signed by Dr. L. Prakash. Dr. S. Prakash and Dr. Yoon, the PPMIR lays out specific steps that are to be followed by the SIO in conducting an inquiry that may lead to an investigation. As you are in possession of the March 3, 2020, letter, which I attach hereto as Exhibit A, I will not reiterate what has already been clearly laid out for you. However, I will state that before you were to start an investigation, you were to conduct an inquiry. At the end of the inquiry, you were to prepare a report as detailed very clearly in the PPMIR on page 10. These elements include (i) a summary of the inquiry process used; (ii) a list of the research records reviewed; (iii) the basis for recommending or not recommending that the allegations warrant an investigation; and (iv) any comments on the draft report by the Respondent or Complainant. Then when you created an inquiry report, you were to provide the findings of the inquiry to Drs. Prakash and Dr. Yoon and allow them to provide their written comments on the findings. Then and only then, you could provide the President of UTMB a copy of the inquiry report. But in doing so, you were also to provide to the President of UTMB the comments from Drs. Prakash and Dr. Yoon. As you are well aware, that is not what happened in the Fall of 2019.

The power to launch an investigation is vested solely in the President of UTMB. Only the President has the power to grant the right to start an investigation, *NOT* the SIO. Additionally, only if the President decides that an investigation is warranted can the SIO provide ORI with the President's written decision, as well as a copy of the inquiry report. Instead of following the clearly defined and simply stated PPMIR procedure, you took it upon yourself to launch in your words an "Investigation" of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. This started in September 2019, four months after the original complaint was filed. You then convened an SIC meeting in December 2019 to determine their guilt. Here again you failed to comply with UTMB's rules set forth in the PPMIR, which clearly state that the investigation committee is to





be formed only after the President of UTMB provides his written approval to start the investigation. Regarding the investigation committee, each of the individuals chosen was to be approved by Drs. Prakash and Dr. Yoon to ensure there was no conflict that would result in a prejudiced decision. Instead, you established an SIC without notifying Drs. Prakash and Dr. Yoon. You then compounded your mistake by failing to provide Drs. Prakash and Dr. Yoon an opportunity to review the SIC member list to provide their feedback and ensure there were no conflicts.

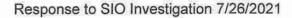
In November 2019, prior to the SIC meeting in December 2019, each of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon sent you a letter. (*see*, Exhibits B – D attached hereto). In these letters, you were provided a reasonable explanation how the error which led to the original Figure S2 occurred. Just as important, you were provided in great detail the measures undertaken by Dr. L. Prakash and Dr. Yoon to ensure a similar mistake *could not occur again*. It is clear by what happened next that you either did not read their letters or you ignored them. What is clear is that you never spoke with any of Drs. Prakash or Dr. Yoon about their letters that were sent to you, the SIO. I also reasonably believe that they were never provided to the President of UTMB or the SIC.

So, you continued your Investigation (your word at the time) and held the SIC meeting in December 2019 where a *judgment* was rendered. Dr. Yoon was to be fired. This was summarized in the "INVESTIGATION REPORT" of January 2, 2020, which is attached hereto as Exhibit E. It is clear from your INVESTIGATION REPORT that you did not read the letters from Drs. Prakash and Dr. Yoon. (*see*, Exhibits B – D). If you had, then the SIC would not have stated as a recommendation on page 3 of your INVESTIGATION REPORT – Recommendations of the SIC.

"that the Department Chair "evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis."

As stated, a process to ensure a similar mistake would not occur had already been implemented and was laid out for you *clearly* in the November 13, 2019, letter from Dr. Yoon. (*see*, Exhibit D). The fact that the SIC is not aware of the implementation of this procedure by Drs. Prakash's lab, clearly shows that you as SIO failed to provide them this critical information prior to the December 2019 SIC investigation meeting.

With the verdict from your investigation in hand, you pass on the verdict from your SIC to Drs. Prakash and Dr. Yoon on February 6, 2020. However, as you should know from the PPMIR, it is the President who decides on the appropriate action to be taken and only after the President determines that the findings substantiate the allegation of research misconduct. As is clear, you as SIO and the SIC had no legal basis to render such a verdict. In rendering a final judgment, you and the SIC *violated* the UTMB PPMIR and as a result you and the SIC caused and continue to cause great harm to Drs. Prakash and Dr. Yoon.





Now for reasons I do not understand, after Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon sent you their March 3, 2020, letter (*see*, Exhibit A) that laid out in detail all of your mistakes regarding the process set forth in the UTMB PPMIR and other issues with the verdict, you did not respond. Indeed, Drs. Prakash and Dr. Yoon did not hear from you again for almost a year when you sent an email to Dr. L. Prakash, as well as Valerie Rosemond and Carolee King, both of UTMB on March 23, 2021. (*see*, Exhibit F attached hereto). In your email, you stated that you had been asked by the Office of Research Integrity if the administrative actions, meaning the verdict rendered by the SIC in the INVESTIGATION REPORT, had been implemented. You then required that Dr. L. Prakash respond to you by March 29, 2021, with the answer.

On March 25, 2021, Drs. L. and S. Prakash responded. (*see*, Exhibit G). They pointed out to you that it was "perplexing" that you had ignored their March 3, 2020, letter, where you were informed in great detail that you *failed* to follow the UTMB PPMIR and *violated* their rights. If you, the SIO, had paid attention to their March 3, 2020, letter, at minimum, you ought to have realized right then that you and the SIC had made a grave error in having informed ORI. It was incumbent upon you at that time to have informed ORI that you had failed to follow the *required* steps of an inquiry under the UTMB PPMIR. You should have informed the ORI that you and the SIC failed to handle this matter properly. Then, you should have withdrawn the report from ORI and apologized to the ORI for your serious mistake. Of course, you and the SIC failed to undertake any of these required steps. As a result, the entire tainted process you pursued and the submission of the report to ORI were illegal, unwarranted, reckless, and extremely damaging to Dr. Yoon and Drs. Prakash.

As you should be well aware, your standard regarding how Dr. Yoon is to be treated for a single honest mistake must be applied to you as SIO and the SIC. Indeed, I would expect that you would agree that you as SIO should not receive preferential or better treatment than Dr. Yoon. Particularly, where you as SIO are charged with knowing the procedures and rules to be followed pursuant to the UTMB PPMIR. Indeed, your failure should be considered worse than Dr. Yoon's honest mistake. As under your own rules there are no do overs, I will continue to call the inquisition you launched and continue to prosecute an Investigation. I will also continue to call the January 2, 2020, verdict, the INVESTIGATION REPORT.

However, I do agree with that part of your statement that the SIC did not find any research misconduct by Dr. L. Prakash or Sr. S. Prakash. I also believe that based on this correct finding, that it was right to close the case against Drs. Prakash. I also understand that the NIH Office of Research Integrity ("ORI") came to the same conclusion in a letter sent to you on June 21, 2021, from Alexander Runko, Director, Division of Investigative Oversight, ORI. (see, Exhibit H attached hereto).





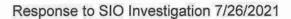
Next, I understand that you sent the INVESTIGATION REPORT to President Ben G. Raimer to request permission to start an investigation into Dr. Yoon. In doing this, you once again failed to allow Dr. Yoon to provide comments for President Raimer to assist in his decision. You also failed to interview Dr. Yoon or Drs. Prakash. So now for a second time, you failed to follow the procedures and rules set forth in the UTMB PPMIR. As you should be able to imagine, this is amazing and perplexing all in one. You were informed of your violation of UTMB's PPMIR almost a year and a half ago. You acknowledge in your discussions with the Director of ORI (your June 3, 2021, letter to the respondents) that you had made a mistake in labeling the SIC Report as an Investigation Report. It can only be assumed that this was based on the information provided by Drs. Prakash and Dr. Yoon. So, the SIO who wants Dr. Yoon fired for a single honest mistake continues to make mistake after mistake, even after being informed of her mistakes.

However, you received the result you wanted. You were able to intentionally mislead President Raimer and obtain his approval of an investigation into Dr. Yoon by gaming the system. You failed to inform President Raimer of your repeated failures to follow the rules as set forth in the UTMB PPMIR. The irony is that your compounded failures fail the standard of what one would hope for regarding a Scientific Integrity Officer of UTMB who is charged with upholding the school's standard of "Integrity."

With President Raimer's improperly attained approval in hand, you next requested that Dr. L. Prakash send you a list of Dr. Yoon's publications over the last five (5) years, which she did. And now, you are continuing your fishing expedition by asking for Drs. Prakash to send you the last five (5) years of their grant applications. To this, I say no on behalf of Drs. Prakash and Dr. Yoon. This inquisition needs to end and if there is an accounting to be had, it is of your incompetent and malevolent conduct and behavior as SIO in this affair. Indeed, it raises the serious question whether the SIO should be the one who is fired.

As stated previously, as SIO you are to follow very specific and simple rules and procedures on how to conduct an inquiry. Then, if reasonable and necessary, and following President Raimer's approval, you can conduct an investigation following the procedures set forth in UTMB's PMIR. You failed in this simple task, not once, but again after having your first failure pointed out to you. You continue to prosecute your inquisition, while failing to follow your own rules.

Further, throughout your inquisition, you have failed to provide an answer to a key component of the inquiry. Why would Dr. Yoon have intentionally created a false Figure S2 if it was not material. Particularly, when he has no history of falsifying data. You never obtained this answer because you never interviewed him on this specific point. If you had, you would have learned it was an honest mistake due to the pressure of working on multiple things at once on his computer as he stated in his November 13, 2019, letter to you. (see, Exhibit D). I would doubt that you or someone working in your lab has not or could not have made a similar mistake under the same circumstances.





Thus, based on the facts in this matter, it is clear that if there is to be an investigation, it should be of you and your conduct as SIO. You have tortured Drs. Prakash and particularly, Dr. Yoon for almost two (2) years with your inquisition for a simple non-material and honest mistake. You have caused each of them great physical, emotional and mental harm and whether you realize it, professional harm. You have done this despite Dr. Yoon letting you know of the great emotional, mental and physical toll your inquisition has taken on him personally. It is clear you do not care for their wellbeing.

Now your behavior and conduct as SIO raises serious legal and administrative issues. This includes your violation of Regents Rules of Conduct, Rule 30103. This rule explicitly states that any employee who, acting singly or in concert with others, obstructs, disrupts, or interferes with any research or other activity authorized to be held or conducted on campus or on property or in a building or facility owned or controlled by The University of Texas System or any of the institutions is subject to disciplinary action, including dismissal. It goes without saying that your willful inquisition, which has not followed the explicit rules and procedures set forth in the UTMB PPMIR has clearly disrupted the research and other activities of Dr. L. Prakash, Dr. S. Prakash, and particularly, Dr. Yoon.

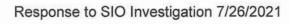
But your violations of the Regents Rules of Conduct do not stop there. Rule 30602 states that

"it is the policy of the University of Texas system or any of the institutions to encourage, fair, efficient, and equitable solutions for problems arising out of the employment relationship and to meet the requirements of State and Federal law."

It goes without saying that the inquisition that you have pursued against Drs. Prakash and Dr. Yoon has not been fair, efficient or resulted in an equitable solution. Instead, it has been wholly unfair, unreasonable, inefficient and just cruel. Particularly, when you consider the improper and illegal judgment of you as SIO and the SIC in the INVESTIGATION REPORT that Dr. Yoon be fired after 16 years of outstanding service for a non-material and honest mistake. In what universe can this be reasonably considered as an equitable solution. Your inquisition has caused Dr. Yoon great mental and physical anguish. It has resulted in serious emotional trauma.

Thus, it goes without saying that your actions over the last two (2) years as SIO of UTMB have resulted in cognizable and significant damage to each of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. So here is what we expect to happen to close this matter. You will provide a letter to Dr. Yoon stating that there is "no evidence" of misconduct by him. This will be shared with President Raimer, the ORI and each member of the SIC. Then you will close this matter.

Failure to take this reasonable step and end this charade will require Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon to consider the legal and administrative remedies available to them. As I am sure you are aware, these include obtaining legal redress for the cognizable harm they have suffered from the actions you as an individual have taken against them personally (clear federal civil rights violations), UTMB and the members of the SIC. It will also include filing a complaint





against you personally as SIO of UTMB with the General Counsel's Office of the University of Texas system for your actions and continued and knowing violation of the Regents Rules of Conduct and UTMB's PPMIR to the significant detriment of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. Other administrative remedies will also be considered.

This whole inquisition should have been terminated following your receipt of the letters from Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon in November 2019. By then the non-material and honest mistake had been corrected and procedures had already been implemented to ensure it would not happen again. But you decided to press your inquisition to the significant detriment of everyone, including UTMB and President Raimer. I expect that this will end now.

Sincerely,

Peter D. Weinstein, Ph.D., J.D.

Managing Partner

Response to SIO Investigation 7/26/2021



EXHIBIT A



6.104 Medical Research Building 301 University Boulevard Galveston, TX 77555-1061 O 409.747.8601

March 3, 2020

Dear Dr. Garg:

This letter is in response to the Investigation Reports you sent to each of us, the Respondents, Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.-H. Y) on Feb. 6, 2020 at 4:14 PM, in which you reproduce the allegations made by the complainant of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our Genes & Development publication, vol. 33, 282-287, 2019. These letters list the members of the UTMB standing SIC involved in both the Inquiry and Investigation and the Summary Statement and Recommendations of the SIC. Given serious issues with the process and significant concerns about the content of this investigation, we object to the recommendations proposed in it, namely dismissal of Dr. Jung-Hoon Yoon from UTMB.

Let me start with our serious concerns about the process. The guidelines of the Policy and Procedure Manual on Integrity in Research (PPMIR) are very clear on the steps that need to be taken in determining the merit of allegations of misconduct; however, as documented below, the proper procedures were not adhered to in this particular case.

Since the guidelines indicate that an inquiry report, which we have not seen and suspect does not exist, should have been sent to the President, we have copied him on this communication; and since we have discussed this matter with the Chair of our Department, we have copied Dr. Mariano Garcia-Blanco as well.

Page 7, section IV E of the PPMIR, states: "During the research misconduct proceeding, the SIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for by law and UTMB policies and procedures."

We did not receive any notices during the proceedings

We list below specific examples where proper procedures were not followed, along with our comments noted in bold:

- (1) Section VI A p.10 of the PPMIR details what the written Inquiry report should contain. Among other items, it should include a summary of the inquiry process used, a list of the research records reviewed, the basis of concluding whether or not an investigation is warranted, and any comments on the draft report by the Respondent or Complainant.
 - We were not provided with any such information and were given no opportunity to comment on the inquiry report.
- (2) Section VI B on p. 10 of the PPMIR states that the SIO shall provide a copy of the inquiry report to the President and to the respondent at the same time and that the respondent has 10 calendar days to send comments to the President regarding the contents of the inquiry report.
 - We were never given a copy of the inquiry report; therefore, we were not allowed the opportunity to send our comments to the President.

- (3) On p. 11 in section VI B of the PPMIR, it states that "The President will determine in writing whether an investigation is warranted."
 - The letters we received from you on Feb. 6, 2020 were entitled "INVESTIGATION REPORT" and state that the SIC members determined there was sufficient ground to proceed to the investigation step. This implies that several steps in the mandated process were not carried out according to the guidelines set forth in PPMIR.
- (4) Once the President has determined that an investigation is warranted, in section VII C, p. 12 of the PPMIR, it states that "The President, in consultation with the SIO and other institutional officials as appropriate, will appoint an investigation committee of at least 3 members..." Thus, the SIC and the Investigation Committee are NOT the same.
 - The bottom of page 1 of the letters we received from you lists the names, etc. of the UTMB SIC members involved in BOTH the inquiry AND the investigation.
- (5) On p. 12, in section VII C of the PPMIR, it states that "The President will notify the Respondent of the proposed committee membership to give the Respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest."
 - We never received any such notification. In fact, as noted above, the SIC committee performed both the inquiry and investigation reports whereas in the email of Sept. 17, 2019 at 1:25 PM, we were notified that it was an inquiry which you would like to complete in 60 days.
- (6) According to p. 13, section VII E of the PPMIR, the investigation committee and the SIO must interview each Respondent and Complainant.
 - None of us, the respondents, were interviewed by the Investigation Committee.
- (7) Section VIII. A on p. 14 provides a list of the elements that the written draft of the investigation report needs to include.
 - No details were provided in the investigation report.

The SIC's actions are even more troublesome in view of the fact that we had provided all the information we were asked for, as noted below.

Your email of Sept. 17, 2019 at 1:25 PM stated that "We would like to complete the inquiry in the next 60 days". In a later email that day (Sept. 17, 2019 at 3:28 PM) you wrote "Please provide us, in defense, documentation for the ability to detect endogenous level of Rev1, DNA Polymerase lota, DNA polymerase kappa in human or other cells used in the study, and original Western blots / images of the original blots, and documentation of the experiments." We, all 3 respondents: Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.H.-Y) provided you with extensive documentation of our ability to carry out these studies in our November 18, 2019 response to you. In addition, we provided the corrigendum for Supplemental Fig. 2 that has been published in Genes & Development. And in our letters (SP & LP), we pointed out the highly error-free track record of Dr. Yoon and we noted that the inclusion of Supplemental Fig. 2 had no bearing on the impact or conclusions of this study.

Between Sept 17 and Nov 18, before we sent you our letters of response, I (LP) communicated with you by telephone several times for advice on what information to include in our response. After

spending many hours examining the complainant's notebooks and comparing relevant pages to the Western Blots (WBs) he referenced, I found many discrepancies which led me to question the validity of his allegations. In the draft of my original response, I had included the following statement: "I want to point out that I spent a lot of time examining the notebooks of the individual making the complaint and I found several instances in which the points brought out by the complainant did not confirm the allegation." We (SP & I) accepted your suggestion to remove this statement because we were given the impression that it was not necessary – thinking that all you needed was the evidence you had asked for in your Sept. 17, 3:28 PM email. Therefore, we were shocked and traumatized to receive your email of February 6 with the attached Investigation Report letters, since we had not been made aware that the Inquiry Phase had progressed to the Investigation Phase.

We (LP & SP) have discussed this situation with our Chair, and respectfully request that the Guidelines of the PPMIR be followed and that the Inquiry and subsequent steps be re-initiated from the beginning. Importantly, I (LP) have uncovered that the majority of the complainant's allegations cannot be substantiated, and it is only if the Inquiry is followed in the proper order that we can discuss these issues with the SIC inquiry committee, and with the Investigation Committee, should it proceed to that stage.

The precipitous action of the SIC and its recommendations, especially the extreme one that Dr. Yoon be terminated from UTMB, without consideration of his excellent track record, path breaking publications, and his devotion to science (for a detailed explanation see our letters that were included in our Nov. 18, 2019 email to you and are attached here) have been extremely devastating to all the respondents. We also feel that no consideration was given to the circumstances under which this error occurred, for which Dr. Yoon has been extremely remorseful, and the steps we have undertaken to avoid such errors in the future (see Section §93.408 Mitigating and aggravating factors in HHS administrative actions, p. 648 of Public Health Service: Policy on Scientific misconduct 42 CFR Part 93).

Content of Allegations

In this communication, we have not addressed in detail the content of the allegations. We will comment on them at the appropriate stage and will do so in great detail.

Thank you very much.

Sincerely,

Louise Prakash

Satyr Prakash

Satyr Prakash

Satyr Prakash

Jung-Hoon Yoon



Response to SIO Investigation 7/26/2021

EXHIBIT B



Subject: Genes & Development paper

November 5, 2019

Dear Committee:

At the outset, I categorically state that I had no knowledge of any issues with the western blots (WBs) shown in Supplemental Figure 2 and I was in no way involved in any of the aspects of constructing this figure.

I have worked closely with Hoon since he joined our group in March 2005. In my long academic career, he is one of the very best colleagues that I have worked with. Hoon has high ethical standards; he cares deeply about discovering the truth and reporting the scientific facts, and his impeccable and impressive first author contributions with us over the past 10 years attest to this fact.

I have thought long and hard about how Hoon, who is such a diligent and highly conscientious individual who repeats experiments too many times to assure the accuracy of his data and conclusions, could end up being responsible for mixing up the information assembled in Supplemental Figure 2. Knowing Hoon as a person and as a scientist as well as I do, knowing the difficult circumstances in which this work was being put together, and the fact that he shares all the important aspects of a project with me, regardless of how negatively that may impact the outcome of the study or its publication, and irrespective of the time he has spent on it, I can affirmatively say that there is absolutely no way that this highly distressing episode occurred because it was in any way intentional.

In the original version of the paper submitted to G&D, we had not included Supplemental Figure 2 because the observation that depletions of respective DNA Pols reduce the frequency of translesion synthesis (TLS) opposite1,N6-ethenodeoxyadenosine (ϵ dA) had provided strong genetic evidence for the effectiveness of siRNA depletions and also because we had published such evidence before. Moreover, since in the revised version, we had included the evidence generated in Rev1- $^{1/2}$ and Pol $^{1/2}$ mouse embryonic fibroblasts (MEFs) that a reviewer had asked for, it was not necessary to include a western blot (WB) figure of siRNA depletions,. Even then I decided to include a WB figure of siRNA depletions in the revised version and asked Hoon for such a figure. I believe that this unnecessary and undue burden I put upon Hoon to assemble such a figure in a short time led to errors in compilation of this figure.

Over the years, Hoon has been working almost single-handedly on a number of novel and path-breaking projects and he has been under pressures which he puts upon himself and the pressures that I put upon him. I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion. Clearly, he did not realize the degree of mental exhaustion or the mistakes he was making when he put the figure together. It is impossible for me to see that Hoon, who cares so deeply about the validity of his results and conclusions, would knowingly misrepresent a figure which has little bearing, if any, on the data shown in the paper or on the conclusions drawn. A person with intent to falsify or misrepresent data would do so for aspects which elevate the impact of the study and not something as marginal as this figure.

In reviewing all the past contributions of Hoon with us, I have become deeply aware of the immense amount of information he puts together in preparation for each paper, and of how error-free and meticulous each of his publications is. Nevertheless, to avoid the possibility of any errors in the future, I will help Hoon in verifying the accuracy of each of the items that are included in the paper. I will also make sure that Hoon is not working on a number of different projects at the same time.

Hoon has been traumatized by the fact that he is responsible for this mishap in the figure. He is a highly devoted scientist who cares deeply about the accuracy and biological relevance of his findings and over the years with us, he has been responsible for a number of pioneering studies published in a number of leading journals, including Cell, Genes & Development, PNAS, and others Moreover, Hoon has been working assiduously on a number of other important projects. I strongly believe that publication of these studies will be highly impactful and paradigm shifting for a number of DNA repair genes which play highly effective roles in protection from breast and ovarian cancers and from leukemias.

Sincerely yours,

Satya Prakash, Ph.D.

Satya Pracash

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology 6.104B Medical Research Building

Telephone: 409-747-8602 e-mail: saprakas@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT C



Subject: Genes & Development paper

November 13, 2019

Dear Committee,

I wish to state at the outset that I was not involved in any way in assembling the data for the gels presented in Supplementary Figure 2. My role was to combine the Supplementary Figure files given to me into one pdf file for submission to the journal, along with the text and text figures.

Both Satya and I were shocked when we learned about the allegation against Dr. Jung-Hoon Yoon, the first author of a manuscript published in Genes & Development in March of this year. It is important to understand the kind of person that Hoon is because then it becomes totally incomprehensible that Hoon could have knowingly and intentionally misrepresented the data in Supplementary Figure 2. He has been with us for the past 14 years, and during that time, I have had ample opportunity to observe the way he conducts himself in his research and how meticulous he is with his data. He is extremely honest, forthright, conscientious, and a most trustworthy, reliable, hardworking, and responsible individual. He always repeats his experiments numerous times to be as sure as one can ever be in science that the data are reproducible and that the conclusions are warranted. The quality and quantity of work that has gone into each of his publications shows that he has accomplished a phenomenal amount of work. He has single-handedly been doing the work that in other labs would be handled by a number of individuals. In fact, one of the reviewers of the recent Cell paper on which Hoon is first author said "This is a monumental work that addresses a key problem in skin cancer and elucidates the roles of Pol0 and other TLS polymerases." (Underline mine). And another reviewer wrote "These data provide unambiguous evidence of skin cancer arising in the absence of UV induced mutations. This is a paradigm-shifting finding as it questions the dogma that UV induced mutations cause skin cancer". In this paper as well as in all his other papers, Hoon has been the prime mover - being responsible for the major aspects of the study.

After going over the details with Hoon it has become clear to me that Hoon was working under tremendous pressure at the time he prepared this figure. He was asked by Satya to provide a figure of western blots showing siRNA knockdowns of the various TLS polymerases used in the study, Hoon made errors because during compilation of a number of western blots, he had many gel images open at the same time, and he picked the wrong images. When Hoon realized what he had done, he was completely devastated. He blamed himself endlessly, and felt strongly that he has brought shame on himself as well as on all others associated with him. It took several days for him to recover sufficiently to be able to address with us the details of how this might have come about. He made a genuine mistake, and I cannot over-emphasize how truly remorseful he has been. This is all because he takes his scientific work very seriously.

I have gone over various ways to reduce the probability of errors arising in the future regarding confusion in identifying western blots or similar types of data. We both agree that annotating each blot with a western blot marker pen such that the date and samples are clearly indicated will be most useful to achieve this end. In addition, applying the same code to the original file

name created by the ImageQuant instrument and to the corresponding blot should avoid any ambiguity as to the identity of the blot. He will also keep a detailed record in a lab notebook where the code name will include an illustrator file of the blot and a legend indicating what is in each lane and the relevant experimental conditions used. From now on, I will carefully go over with Hoon's record keeping in this regard and I am confident that this strategy will serve to avoid mistakes in the future.

We have compiled a new Supplementary Figure 2 and have sent this figure to Genes & Development to be published as a Corrigendum. I have been corresponding with Dr. Laureen Connell, Senior Editor, Genes & Development, regarding the corrigendum and there do not seem to be any issues with replacing the figure. The emails from Dr. Connell are included with the materials provided to the committee.

Thank you for giving us the opportunity to explain the circumstances that led to mistakes in the compilation.

Sincerely yours,

Louise Prakash, Ph.D.

Laure Propost

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology

6.104A Medical Research Building

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT D



November 13, 2019

Letter of Explanations to Scientific Integrity Committee

In going over Supplementary Figure S2, I have realized that I failed to keep a record of how I had compiled this figure and it has become clear to me that I made errors in assembling this figure. I am always very concerned about the accuracy and repeatability of my data and I have been extremely upset about not being careful in assembling this figure I want to emphasize that all these mistakes are unintentional errors and I wish to explain the circumstances under which this figure was made.

I joined the Prakash lab in 2005 with a specific purpose of studying translesion synthesis (TLS) mechanisms in human cells. For this purpose, I designed a novel duplex plasmid system in which replication through a site-specific DNA lesion present on the leading or the lagging DNA strand could be analyzed methodically. For determining the contribution of various TLS polymerases (Pols), I began using siRNA depletion method as this approach avoids the complications of genetic suppression or other genetic artifacts that accompany null mutations. After over two years of effort, I established the plasmid system and optimized the efficient siRNA depletion conditions for a number of TLS Pols in human and mouse cell lines. To confirm the efficient siRNA depletion of TLS Pols in mammalian cells, I used western blot analysis and if necessary, RT-PCR. The establishment of these approaches has allowed me to systematically analyze the genetic control of TLS opposite different types of DNA lesions in human cells and these studies have been published in prestigious scientific journals.

When I prepared the Figure S2 for the Genes & Development paper, I was working under tremendous pressure of time and of having to deal with a number of different ongoing studies. Moreover, in the last year I had taken over the work of post-docs who had left the laboratory. At the same time, I was handling a rather complex paper for Cell, and when Satya wanted me to provide a new figure for siRNA depletions, because of the concern for the revision deadline, I rushed to finish the figure. I opened many files of western blot images on the computer screen and because of lack of attention and confusion, I mixed up the files and didn't double check the final figure before submission. I do realize that there is no excuse for my making these mistakes; from now on, I will be much more careful so that such mistakes never happen again.

To avoid such errors from occurring in the future, I have discussed a strategy with Louise which I plan to follow. Our laboratory uses the ImageQuant LAS4000 camera system for obtaining digital images of our western blots of other samples. The digital images are produced by exposing the blot to chemiluminescence and the system automatically names the file with the date it is created. From now on, for each file genrated by the ImageQuant, I will add a code name to each corresponding blot using a western blot marker pen so that there will be no ambiguity as to the identity of the samples in a particular blot. In addition to annotating each blot with the date and sample name, I will keep a detailed record of each blot in a notebook where every lane of the particular blot will be clearly labeled as to what sample is in each lane, what antibody was used, and any other pertinent experimental details. Blots will not be copied into adobe illustrator until they have been clearly marked. We expect that this procedure will substantially reduce the probability of error. In addition, I will consult with Louise and show her my annotation system so that there will be no confusion as to what each blot represents.

Thank you very much for considering my explanation of the circumstances that led to this unfortunate, and entirely unintentional, incident for which I take full responsibility.

Sincerely yours,

Jung-Hoon Yoon, PhD

Research Scientist

Biochemistry and Molecular Biology

6.108 Medical Research Building

Telephone: 409-747-8604; e-mail: juyoon@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT E

University of Texas, Medical Branch in Galveston ("UTMB")

Confidential Sensitive

Allegations of Research Misconduct Respondent: Prakash Satya, PhD

Date of SIC Meeting: December 19, 2019

Report Date: January 2, 2020

1. INVESTIGATION REPORT

1.a. Background and summary of Inquiry

In a message dated May 5, 2019, allegations of research misconduct were raised by a complainant. The allegations stated possible research misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019).

Panel A - top left: blot for TLS Pol in NC/Poln samples is from another blot for a different protein.

Panel A - middle left: Polφ data is from another blot for a different protein in different cells, Rev1 blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Polt data are from a blot for another protein.

Panel B- Western blot for Pol ι and tubulin for NC/Pol ϕ samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data. This manuscript cites support from US PHS funds, specifically NIH grants ES022948 and GM126087 (PI: Prakash).

Though the complainant identified Yoon, Jung-Hoon, PhD, Research Scientist in the Department of Biochemistry and Molecular Biology (BMB) as respondent. Dr. Yoon was identified to directly report to Dr. S Prakash. Thus, Dr. S Prakash was also identified as respondent.

Dr. NJ Garg Scientific Integrity Officer (UTMB) met the complainant in May 2019 and received the material justifying the allegation. The material received from complainant is attached as **Appendix 1**.

Dr. Garg (and Ms. Bricker) met Dr. Yoon, Dr. S. Prakash and Dr. L Prakash (identified as respondents) on Sept 16 and Sept 17 to present the allegation. Notebooks and computer hard drive were sequestered on September 16. The Scientific Integrity Committee members determined there is sufficient ground to perform investigation.

The Investigation

1.b. Names, titles and CVs for UTMB SIC members involved in Inquiry and Investigation.

The members of the UTMB standing SIC are listed below. The biosketches of the members are available on request.

Dr. Nisha J Garg, PhD MBA (Professor, Microbiology & Immunology, School of Medicine (SOM) and Scientific Integrity Officer)

Dr. Giulio Tagliatela, PhD (Professor, Neuroscience, SOM and Chair, SIC)

Dr. David H Walker, PhD (Professor, Pathology, SOM)

Dr. Lorraine Evangelista, PhD (Professor, School of Nursing)

Dr. Blake Rasmussen, PhD (Professor, Nutrition and metabolism, School of Health Professions)

Dr. Rebeca Wong, PhD (Professor, Preventive Medicine and Community Health, SOM)

Dr. B Monte Pettitt (Professor, Biochemistry & Molecular Biology, SOM)

Dr. V Suzanne Klimberg (Professor, Surgery, SOM)

Ms. Carolee A King (JD Senior Vice President & General Counsel, ex officio member)

Ms. Kimblyn Raschke / Ms. Nancy Bricker (Administrative support, ex officio)

1.c. Names and titles of all respondents:

Respondent S Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent L Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent Yoon, Research Scientist, Biochemistry and Molecular Biology, UTMB

1.d. Attorneys if relevant: None

1.e. PHS support/ORI jurisdiction.

The following grants funded by NIH were cited in the publication:

Paper Grants

Paper: Genes & Development 33:282-287 (2019) ES022948 and GM126087

2. Investigation process:

Dr. Garg and Ms. Bricker met the respondents on Sept 6-7, 2019 to present the allegation and sequester the relevant notebooks and hard drive.

The respondent L Prakash kept contact with Dr. Garg through emails and phone calls and provided detailed response on November 18, 2019. The statements received from all respondents are attached as **Appendix 2**. Respondent has also provided new data (**Appendix 3**) and communications with the journal (**Appendix 4**).

The collected information and data were sent to the members of the SIC investigation committee electronically on 11/19/2019. Members discussed the case electronically and formally met on December 19, 2019.

The presented report was approved by SIC members by January 25, 2020 and the legal counsel on February 6, 2020.

3. Summary:

Dr. S Prakash (respondent) states, "I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion". Dr. S Prakash (respondent) maintains that it was an honest error of Dr. Yoon.

All respondents could not identify the original gels that were used to submit Figure S2. Lacking that, all experiments/WB for Figure S2 were repeated, and new data were utilized to assemble new Figure S2 (attached as Appendix 3). The newly generated Figure S2 was sent to the G&D journal (Appendix 4). The journal accepted to publish revised version of the Figure S2 as corrigendum.

Scientific Integrity Committee: The person who ran Western blots in the lab has moved to another location. His folders were sequestered and found to be appropriately labeled with all details and needed information. However, the data presented in S2 Figure were found to be cut from images that belonged to data collected with other antibodies. Dr. Yoon was directly involved in assembling the data for publication and he accepted the responsibility for mis-presentation of data. Dr. S Prakash was not identified to have direct knowledge of mis-presentation of data.

SIC members unanimously concluded that falsification and fabrication of data occurred. SIC members considered that a lack of supervision and over-confidence in the capabilities of Dr. Yoon likely resulted in mis-presentation of data. However, SIC members concurred that there is no evidence that suggest that Dr. Prakash had direct knowledge of mis-presentation of data and he was likely not involved in falsification and fabrication of the data presented in Figure S2.

- 4. Recommendations of the SIC: Members of the SIC recommended the following:
 - 1. SIC members request the Chair of the Department to evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis. It will be essential that PI is aware of and has confirmed the accuracy of all raw data to be used for future publications.
 - 2. Notification to the Office of Research Integrity and Federal Funding Agency.
- 5. Notice to the respondent of the institutional decision and administrative action. Pending

Submitted by:

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston

O: 409-747-6865, E: nigarg@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT F

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From: Garg, Nisha <nigarg@utmb.edu> Sent: Tuesday, March 23, 2021 4:26 PM

To: Prakash, Louise <loprakas@UTMB.EDU>; Prakash, Satya <saprakas@UTMB.EDU>

Cc: Rosemond, Valerie S. <vsrosemo@UTMB.EDU>; King, Carolee A. (Legal) <caaking@UTMB.EDU>

Subject: G&D paper

Hello Louise and Satya. I have been asked by the office of research integrity to address if the administrative actions recommended in Scientific Integrity Committee report are implemented. For this purpose, I request you to let me know the current employment status of Dr. Hoon and the lab procedures/protocols that are implemented/followed to ensure proper recording of the data and gel images in the lab.

Please send your response by Monday March 29th at the latest. Thank you

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer Professor, Microbiology & Immunology University of TX Medical Branch at Galveston O: 409-747-6865; E: nigarg@utmb.edu



Response to SIO Investigation 7/26/2021

EXHIBIT G

Prakash, Louise

From:

Prakash, Louise

Sent:

Thursday, March 25, 2021 2:27 PM

To:

Garg, Nisha

Cc:

Raimer, Ben G.; García-Blanco, Mariano A.; Rosemond, Valerie S.; King, Carolee A. (Legal)

Subject:

RE: G&D paper

Attachments:

Response to Investigation Report letters

Importance:

High

Dear Nisha,

We find your communication of March 23, 2021 (4:26 PM) perplexing because we had sent you an email letter over one year ago, on March 3, 2020, documenting in great detail our serious concerns regarding the allegation of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our *Genes & Development* publication (2019, vol. 33, 282-287). In addition to sending that email and the attached materials to you, we had copied President Ben Raimer and our Chair, Dr. Mariano Garcia-Blanco. As you will note in that email (which is attached here), we expressed our concerns in detail and cited numerous examples of how procedures described in the <u>Policy and Procedure Manual on Integrity in Research (PPMIR)</u> of the University of Texas Medical Branch at Galveston had not been followed. Since we did not hear from you, we assumed that the matter had been closed. We have discussed this matter again with Dr. Garcia-Blanco and he shares our concerns.

Dr. Yoon's employment status at UTMB remains the same and he continues to make seminal contributions to translesion DNA synthesis mechanisms. Also, we stress that for each experiment we have been following very methodical and stringent procedures to ensure proper recording of the data and gel images.

Sincerely,

Louise Prakash, Ph.D.

Professor, Department of Biochemistry and Molecular Biology
I.H. Kempner Professor in Human Genetics
loprakas@utmb.edu

Satya Prakash, PhD.

Professor, Department of Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences saprakas@utmb.edu Response to SIO Investigation 7/26/2021



EXHIBIT H

DEPARTMENT OF HEALTH & HUMAN SERVICES



Office of the Assistant Secretary for Health Office of Research Integrity 1101 Wootton Parkway, Suite 240 Rockville, MD, 20852

> Phone 240-453-8800 FAX 301-594-0043

Email: alexander runko whhs gov Web https ori dhhs gov

CONFIDENTIAL/SENSITIVE

June 21, 2021

Nisha Jain Garg, Ph.D., MBA Scientific Integrity Officer Professor, Microbiology & Immunology University of Texas Medical Branch 301 University Blvd. Galveston, TX 77555-0342

TRANSMITTED VIA EMAIL TO: nigarg/a utmb.edu

RE: ORI 2021-18 (DIO 7323)

Dear Dr. Garg:

The Division of Investigative Oversight (DIO), Office of Research Integrity (ORI), has reviewed the report of the inquiry conducted by the University of Texas Medical Branch in Galveston (UTMB) into allegations of possible research misconduct against Louise Prakash, Ph.D., Professor, Department of Biochemistry and Molecular Biology, UTMB. Dr. Prakash allegedly falsified and/or fabricated data in a supplementary figure in one (1) published paper. The questioned paper cited support from U.S. Public Health Service (PHS) funds, specifically National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES022948 and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM126087.

DIO concurs with UTMB's determination that there is insufficient evidence against Dr. Louise Prakash to warrant proceeding to an investigation. Therefore, DIO has administratively closed this case without further action.

Consistent with Federal law and ORI policy, research misconduct proceedings that result in no PHS finding of misconduct remain confidential for ORI. We ask that you respect this policy. We appreciate your reporting to DIO under 42 C.F.R. § 93.309.

¹Yoon J-H, Johnson RE, Prakash L, Prakash S. DNA polymerase θ accomplishes translesion synthesis opposite 1,N°-ethenodeoxyadenosine with a remarkably high fidelity in human cells. *Genes Dev.* 2019 Mar 1;33(5-6):282-87.

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ORI 2021-18 (DIO 7323)

Page 2

If you have any questions about this matter, please contact me at alexander.runko@hhs.gov or 240-453-8800.

Sincerely,

Alexander P.

Digitally signed by Alexander P.

Runko -S

Runko -S

Date: 2021.06.22 16:34:42 -04'00'

Alexander Runko, Ph.D.

Director

Division of Investigative Oversight Office of Research Integrity

Exhibit II

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Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D.
Phone: 805-444-7865
Fax: 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

September 23, 2021

Daniel H. Sharphorn Vice Chancellor and General Counsel University of Texas 210 West 7th Street Austin, TX 78701 Tel: (512) 499-4462

Fax: (512) 499-4523 dsharphorn@utsystem.edu

Dear Mr. Sharphorn,

I will start by saying that I fully understand that sending this letter to you is out of the ordinary course of business in a matter like the one I will address below. However, it is the last chance I can see that will prevent a lawsuit by my clients Dr. Louise Prakash, Dr. Satya Prakash (collectively "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") against the University of Texas ("UT"), the University of Texas Medical Branch ("UTMB") and multiple individuals from UT and UTMB. The genesis of this matter relates to a botched and dare I say, maliciously handled inquiry into a mistake by Dr. Yoon that has been conducted by Dr. Nisha Garg ("Dr. Garg"), the Scientific Integrity Officer ("SIO") of UTMB. Dr. Garg's malicious efforts have been supported and countenanced by UTMB's legal department and UTMB President Raimer.

This investigation relates to a supplemental figure in a paper published by Drs. Prakash and Dr. Yoon in Genes & Development in 2019. While revising the paper during the publication process, a supplemental figure was added to the paper that did not contain the correct gels. This supplemental figure was not material to the findings, conclusions or results of the paper. When this mistake was pointed out to Drs. Prakash and Dr. Yoon in September 2019, it was immediately corrected and a corrigendum was published by the journal. It is important to note that the publishing journal had no issue with the correction and the paper was not retracted. Additionally, Drs. Prakash and Dr. Yoon implemented procedures to ensure such a mistake would not occur again in the future. This should have ended this matter. Unfortunately, Dr. Garg and others at UTMB had only begun their two-year malevolent process.

Between September and November, 2019 Dr. Garg was made aware in multiple letters of the corrigendum and the changes made in the handling of data going forward in the laboratory of Drs. Prakash. Dr. Garg was also made aware that the mistake was an honest one by Dr. Yoon. However, it is clear from the written record that Dr. Garg either ignored the letters sent to her or did not read them. Instead, Dr. Garg met with the Scientific Investigation Committee ("SIC") to



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investigate Drs. Prakash and Dr. Yoon. The committee met in December, 2019 and in January, 2020 prepared and sent to Dr. Garg an Investigation Report. The Investigation Report called for Dr. Yoon to be terminated immediately. What is interesting is that the Investigation Report also stated that changes were to be made in handling of data in Drs. Prakash's lab, changes that had been implemented months before the SIC met and detailed in the aforementioned letters. This suggests that Dr. Garg failed to provide the written communications containing the exculpatory information provided by Drs. Prakash and Dr. Yoon to Dr. Garg between September and November, 2019 to the SIC, which met in December 2019.

The report was provided to Drs. Prakash and Dr. Yoon in February, 2020. In response, in March, 2020 Drs. Prakash and Dr. Yoon sent Dr. Garg a letter setting forth that Dr. Garg's "investigation" had violated the UTMB' Policy and Procedure Manual of Integrity in Research ("PPMIR"). Our subsequent review has also determined that she also violated multiple sections of 42 CFR § part 93 and the UT Regents Code of Conduct. These include, at a minimum, 42 CFR §93.301(b)(2), 42 CFR §93.302(a)(2)(i – ii), 42 CFR §93.304(b, e and f), 42 CFR §93.305(b), 42 CFR §93.307(a)(1 – 3), 42 CFR §93.307(d)(1 – 2), and 42 CFR §93.307(e – g) and Regents Rules of Conduct Rule 30103 and 30602. The latter violations were identified and pointed out to Dr. Garg, UTMB's legal department and President Raimer on July 26, 2021 and September 16, 2021. To date none of the aforementioned individuals or departments has taken any action to remedy this situation

After sending the March, 2020 letter Drs. Prakash and Dr. Yoon did not hear from Dr. Garg for a year. Then in March, 2021 Dr. Garg sent an email asking Dr. Louise Prakash to confirm that she had fired Dr. Yoon. Drs. Prakash responded a couple of days later stating that they found Dr. Garg's email "perplexing" and pointed out how surprised they were that Dr. Garg had ignored the issues with her investigation detailed in their March, 2020 letter. It was about two and half months later that Dr. Garg wrote to Drs. Prakash and Dr. Yoon that she realized that a mistake had been made in labelling the report by the SIC an "Investigation Report." Dr. Garg then wrote that the "Investigation Report" would now be called an "Inquiry Report," with the only difference being that she had taken out Section 4, which called for Dr. Yoon to be fired. This "Inquiry Report" was sent to UTMB President Raimer who approved the implementation of a formal investigation of Dr. Yoon.

What happened here is flawed in so many ways. First, the process followed by Dr. Garg and UTMB President Raimer still continued to violate the inquiry process set forth in the UTMB PPMIR, several sections of 42 CFR part 93, and the Regents Rules of Conduct. Next, it does not take a genius to determine that removing the conclusion from the original "Investigation Report" and relabeling it an "Inquiry Report" creates an inherent conflict of interest. Either Dr. Garg's investigation finds Dr. Yoon guilty and declares he should be fired, so that the investigation process reasonably appears to have come to a preordained conclusion, or Dr. Yoon is found rightfully innocent and Dr. Garg, UTMB's legal department and UTMB President Raimer have put Dr. Yoon as well as Drs. Prakash through an unwarranted and malicious two-year hell period, with the damage it created. Amazingly, as of the date of this letter neither Dr. Garg,



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UTMB's legal department, or UTMB President Raimer have conceded this conflict of interest even after it was pointed out to them.

So continuing the hell-scape drama, at the end of June, Dr. Garg let Drs. Prakash and Dr. Yoon know that the investigation of Dr. Yoon was now official per the decision of UTMB President Raimer and that Drs. Prakash were to produce papers and grants for the last five years that included Dr. Yoon. At this point, I intervened on behalf of Drs. Prakash and Dr. Yoon and sent Dr. Garg a long letter on July 26, 2021 detailing all of the issues with the handling of this matter by her, UTMB's Legal Department (e.g. Carolee A. King) and President Raimer. I included the aforementioned correspondence as attachments to that letter. I have attached my July 26, 2021 letter with its attachments to the email. It was not until September 2, 2021 that Dr. Garg responded to my letter. In her letter she ignored everything I had stated about her failures to follow the PPMIR and her violations of the UT Regents Code of Conduct. She stated that the investigation would continue under her direction.

At this point it was clear that it did not matter to Dr. Garg or anyone at UTMB that the process they were following violated UTMB's PPMIR, several sections of 42 CFR part 93 and the UT Regents Code of Conduct. Knowing that my clients could not receive fair treatment at UTMB and that everyone from UTMB President Raimer and UTMB's Legal Department on down were biased, prejudiced and clearly did not care that they were causing Drs. Prakash and Dr. Yoon great harm and cognizable damage, I then reached out to Ana Vieira Ayala, Assistant General Counsel in the UT General Counsel's Office on September 10, 2021. I left Ms. Ayala a voice mail asking her to call me as I wanted to discuss serious issues related to my clients at UTMB. Though I did not explicitly state that I was making the call as a Whistle Blower, I fully expected that she would call me back so I could discuss this matter with her. I also reasonably believed that Ms. Ayala understood and appreciated that my message constituted one by a Whistle Blower. Instead, Ms. Ayala contacted Ms. Bremond who heads UTMB's litigation group. I was and continued to be surprised that Ms. Ayala took this step without calling me first to find out why I had called. It has had the effect of "outing the Whistle Blower" and making matters worse for Drs. Prakash and Dr. Yoon at UTMB.

So, Ms. Bremond called me on September 10, 2021 and was impatient and generally pretty nasty. I also believe that she lied to me during the call about her knowledge of the matter regarding Drs. Prakash and Dr. Yoon. After my call with Ms. Bremond, I expected to hear back from her within a few days that Dr. Garg was no longer running the investigation. Surprisingly, I have heard nothing. This prompted me on September 16, 2021 to send Ms. Bremond an email stating that my clients had reached the end of their rope and that this entire process had to end or my clients would have to take any legal and administrative actions available to them. As of today, I still have heard nothing from Ms. Bremond or anyone else at UTMB.

So this brings me to the reason I have sent this letter to you. It is clear to me that there is no means of receiving a fair and nonprejudicial resolution to this matter with anyone at UTMB. In our eyes they are all corrupted. Thus, I am sending this letter to you in a last hope to resolve this



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matter short of litigation. It is my hope that you can intervene in this matter and put things right. That would mean at a minimum, immediately moving this matter out of UTMB and reasonably closing it expeditiously following an unbiased, nonprejudicial review of the facts. Anything less is unacceptable to Drs. Prakash and Dr. Yoon. In the end, Drs. Prakash and Dr. Yoon have suffered great emotional, physical, reputational and other damages; including, this whole malicious matter having a negative effect on their ability to conduct their research. It is our hope that you can end their suffering.

As a courtesy, I have attached the correspondence and the Investigation Report to this letter for your review if you do not already have them. I look forward to your prompt reply and if necessary, I am available to meet you in person to resolve this matter.

Best regards,

Peter D. Weinstein

Enclosures

Exhibit III

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Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D.
Phone: 805-444-7865
Fax: 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

October 25, 2021

Alexander Runko, Ph.D.
Director
Division of Investigative Oversight
Office of Research Integrity
1100 Wooten Parkway
Suite 240
Rockville, MD, 20852
Tel: (240) 453-8800

Alexander.runko@hhs.gov

Dear Dr. Runko,

I am sending this letter to you to bring to your attention the illegal behavior, gross negligence and willful misconduct of Dr. Nisha Garg ("Dr. Garg"), the now former Scientific Integrity Officer ("SIO") of the University of Texas Medical Branch ("UTMB") located in Galveston. As you are aware, my clients Dr. Louise Prakash and Dr. Satya Prakash (collectively, hereinafter referred to as "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") have been subjected to an over two-year long "investigations" led by Dr. Garg, which still continues against Dr. Yoon.

After over two years of Dr. Garg's "investigations," my clients engaged me to help defend them. As will be described in more detail below, I tried to reason with Dr. Garg shortly after my engagement. I raised all of the issues that Drs. Prakash and Dr. Yoon had previously brought to her attention in written communications in November 2019, and March 2020, that relate to her illegal behavior, gross negligence and willful misconduct, including the violation of UTMB's Policy and Procedure Manual of Integrity in Research ("PPMIR"). In particular, the PPMIR sets forth the process of first an inquiry and then, if warranted, an investigation. The PPMIR also sets forth the rights of the accused during the inquiry and then the investigation process. Dr. Garg failed to follow any of the process or other rules in the PPMIR during the over two-year period of her investigations, which started in May 2019 and recently ended in October 2021. I also raised additional concerns based on her violation of the UTMB Regents Code of Conduct and her violations of 42 CFR Part 93 in July 2021 and September 2021 written communications sent by me. However, despite having her failings pointed out to her on multiple occasions, she continued to move forward with her never ending "investigations."

Dr. Garg's failure to listen to reason forced me to raise her illegal actions, other failures, and her unethical and immoral behavior with Daniel Sharphorn, Vice Chancellor and General Council of the University of Texas System. (Letter to UT GC Sharphorn attached as Exhibit A). I am not



sure you are aware, but Dr. Garg is no longer the SIO of UTMB, which we reasonably believe is due to my clients' raising their issues with her handling of the "investigations" over the last over two plus years to General Counsel Sharphorn. (Announcement of Dr. Niesel as UTMB's new SIO attached as Exhibit B). Additionally, with her termination as SIO, Dr. Garg's latest "investigation" has been terminated and a new inquiry initiated with the new SIO at UTMB. (Email from C. B. Woodgett attached as Exhibit C). Though my clients do not believe such an inquiry is merited and have serious and reasonable concerns about the fairness of any inquiry run out of UTMB, they believe that this inquiry will come to the result that should have happened two years ago – the mistake was an honest one and did not rise to the level of research misconduct.

Now, as will be discussed in more detail below, during her over two-year "investigations" (I contend actually three attempts at the inquiry/investigation process¹), Dr. Garg has repeatedly violated UTMB's PPMIR. Dr. Garg has also repeatedly violated multiple sections of 42 CFR § part 93. Dr. Garg continued with this behavior even after her violations were specifically and explicitly pointed out to her and others at UTMB. My clients and I also reasonably believe that Dr. Garg's purposefully and repeatedly failed to inform you and likely others at the National Institute of Health ("NIH") Office of Research Integrity ("ORI") of my client sand my written communications to Dr. Garg that pointed out in clear language her failures and illegal behavior. My clients and I reasonably believe that Dr. Garg failed to share our written communications with the NIH ORI in order to obtain the ORI's alleged request to initiate an investigation into Dr. Yoon. (Dr. Garg letter September 2, 2021, attached as Exhibit D)

It is because of the complete loss of institutional control over Dr. Garg and her clear bias and prejudice against Drs. Prakash and Dr. Yoon that I take this extraordinary action and reach out to you directly so that you and the NIH ORI are aware that D Garg has committed fraud and other illegal actions (including violations of UTMB's PPMIR, the University of Texas's Regents Code of Conduct and several sections of 42 CFR Part 93) against the NIH ORI and my clients. We believe that these actions require that the NIH ORI initiate an immediate inquiry and investigation into the actions of Dr. Garg and those who supported the hierts and I also believe that the NIH ORI should take all actions available to bring some semblance of justice to this seriously unfortunate situation. We make this request based in part on the damage that Dr. Garg's illegal, malicious and willful actions have caused Drs. Prakash and Dr. Yoon. Each has suffered great mental, emotional and physical stress over the last two years for a situation that should have ended long ago. (Parg's actions have also seriously and will continue to cause reputational harm to the detriment of Drs. Prakash and Dr. Yoon. Finally, Dr. Garg's actions

¹ Drs. Prakash and Dr. Yoon reasonably believe that the first sham investigation started in May 2019 and went until May 2021, when it appears Dr. Garg finally read the email from Dr. Louise Prakash from March 2021 and Drs. Prakash and Dr. Yoon from March 2020. The second sham investigation started in June 2021, with the letter from Dr. Garg to Dr. Louise Prakash telling her that the Investigation Report was now an inquiry report, and the investigation was approved by UTMB President Raimer and the third sham investigation started on September 12, 2021with the letter from Dr. Garg to Dr. Peter D. Weinstein.



have led Drs. Prakash to have concerns about how this matter will affect their ability to continue to receive research grants from the NIH.

Now, I am sending this letter to you in part because in Dr. Garg's letter to me on September 1, 2021 (attached to this email as Exhibit D), she personally implicates the NIH ORI as formally instructing her to initiate the third "investigation" by claiming that the NIH ORI told her to use her January 2, 2020, Investigation Report as the **bratilization** new investigation. According to Dr. Garg, the NIH ORI instructed her to remove the judgment to fire Dr. Yoon from the January 2, 2020, Investigation Report and relabel the Investigation Report an Inquiry Report. Specifically, Dr. Garg states in her September 2 letter that:

"UTMB has been in communication with the Office of Research Integrity ("ORI"), which oversees scientific integrity on behalf of the Secretary of Health and Human Services and has been advised by ORI's Division of Investigative Oversight ("DIO") to proceed with the investigation into Dr. Yoon by treating the mislabeled "Investigation Report" dated January 2, 2020 as an "Inquiry Report" and disregarding the recommendations contained therein as premature." (emphasis added)

I do not know if you and the ORI actually told Dr. Garg to initiate the investigation into Dr. Yoon, but if you did, it is my belief along with that of Drs. Prakash and Dr. Yoon that this decision was made because Dr. Garg failed to provide the NIH ORI DIO with all of the relevant information.

To give you some background, I am attaching the letter I sent to Dr. Garg on July 26, 2021, that sets forth in great detail many of Dr. Garg's violations (my July 26, 2021, letter attached to this email as Exhibit E). Attached to the July 26 letter are correspondence starting in September 2019 and going through June 2021 between Dr. Garg and Dr. Louise Prakash, Dr. Satya Prakash and Dr. Yoon. I would ask you as a courtesy to read my letter to Dr. Garg and the attached correspondence. What you will find is that by November 2020, my clients had explained that the mistake was an honest one and that they had already taken steps to ensure it could not happen again. Additionally, the mistake was not material to the results, findings, and conclusions of the published paper. In fact, the journal Genes and Development had allowed them to correct the mistake through the publication of a corrigendum².

Further, it is clear through her actions since November 2019, that Dr. Garg either did not read the written communications from my clients that were attached to my July 26, 2021, letter or purposefully ignored them. My letter details Dr. Garg's failure to follow the UTMB PPMIR inquiry. My letter further points out that even after Dr. Garg was appraised of her violations of the UTMB PPMIR by Drs. Prakash and Dr. Yoon in March 2020, she ignored her violations and

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² It is noteworthy that the journal Genes and Development has recently published a new paper recently submitted by Drs. Prakash and Dr. Yoon. From this it is clear that the journal that published the correction does not believe that Dr. Yoon committed research misconduct as it begs reality that if the publishers had that belief that they would have agreed to publish their new paper.



then willfully continued to violate the procedures of the UTMB PPMIR by continuing with her sham inquiry and investigation. Next, as stated in my letter, Dr. Garg's actions violated the University of Texas' Regents Code of Conduct.

Additionally, though not addressed in my letter to Dr. Garg, but addressed later in an email to Carolanda Bremond Woodgett, Head of Litigation at UTMB, Dr. Garg's failures further violated federal law. More particularly, Dr. Garg violated multiple sections of 42 CFR Part 93. For instance, Dr. Garg has clearly violated and continues to violate at a minimum: 42 CFR §93.301(b)(2), 42 CFR §93.302(a)(2)(i – ii), 42 CFR §93.304(b, e and f), 42 CFR §93.305(b), 42 CFR §93.307(a)(1 – 3), 42 CFR §93.307(d)(1 – 2), and 42 CFR §93.307(e – g).

Based on all the evidence, it is immutable that Dr. Garg is not an ethical or moral person and had no issue continuing with her sham "investigations" despite her misguided actions being repeatedly pointed out to her. In this regard, beyond her failures and violations of the UTMB PPMIR, 42 CFR § part 93 and the University of Texas' Regents Code of Conduct, it is Dr. Garg's ethical and moral failures that also need to be looked into by the NIH ORI. Indeed, one has to wonder whether based on her repeated and willful failures and material violations, Dr. Garg should be allowed to continue to receive NIH grant funding. With her recent termination as SIO, it is clear that even UTMB no longer finds that she is fit to continue in her former role based on her past behavior. In fact, in law, UTMB's termination (constructive or actual) as SIO should be considered an admission against interest. In simple terms this means that UTMB found Dr. Garg's actions in her dealings with Drs. Prakash and Dr. Yoon raiseable enough to have terminated her as SIO.

In the end, what gets lost in Dr. Garg's ethical, moral and material failures, illegal actions and other violations is that this whole affair has been over an honest mistake by Dr. Yoon. As stated, it is incontrovertible that Dr. Yoon's mistake was neither material to the results, findings or conclusions of the paper. In fact, the publishing journal merely corrected it with a corrigendum. Additionally, as Dr. Garg is aware, immediately upon learning of Dr. Yoon's honest mistake, Dr. Yoon and Dr. Louise Prakash immediately put into effect new procedures to ensure a similar mistake would not be made again. Dr. Garg was made aware of these new procedures in a letter from Dr. Yoon and Dr. Louise Prakash in November 2019 prior to her initiating the improper "investigation" in December 2019, that resulted in the January 2, 2020, Investigation Report. However, based on the January 2, 2020, Investigation Report it is clear that Dr. Garg purposefully failed to provide Drs. Prakash's and Dr. Yoon's exculpatory evidence that they had provided to Dr. Garg to the UTMB Scientific Integrity Committee ("SIC") that prepared the Investigation Report. The result was that the SIC in the January 2, 2020 communication recommended that Dr. Louise Prakash institute a policy to make sure the honest mistake did not occur again. However, this policy had already been implemented as disclosed to Dr. Garg by Dr. Yoon and Dr. Louise Prakash in their November 2019 letters. Thus, it is clear that this letter, and likely none of the other written communications provided by Drs. Prakash and Dr. Yoon were provided to the SIC before they prepared their improper January 2, 2020, Investigation Report.



Finally, I understand that the NIH ORI has discretion over whether to take action against Dr. Garg based on the allegations made in this letter and the supporting evidence. However, it is the belief of Drs. Prakash, Dr. Yoon and myself that based on the evidence I have provided and UTMB's own action in terminating her as SIO that there is sufficient justification for the NIH ORI to look into this matter and take all appropriate actions.

I appreciate your time in reviewing this letter and the attachments hereto. If you have any questions, you should feel free to reach out to me directly. I can also put you in touch with Dr. Louise Prakash, Dr. Satya Prakash or Dr. Yoon.

Best regards,

Peter D. Weinstein

Enclosures

Exhibit A

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 305 of 514



Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D.
Phone: 805-444-7865
Fax: 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

September 23, 2021

Daniel H. Sharphorn Vice Chancellor and General Counsel University of Texas 210 West 7th Street Austin, TX 78701 Tel: (512) 499-4462

Fax: (512) 499-4523

dsharphorn@utsystem.edu

Dear Mr. Sharphorn,

I will start by saying that I fully understand that sending this letter to you is out of the ordinary course of business in a matter like the one I will address below. However, it is the last chance I can see that will prevent a lawsuit by my clients Dr. Louise Prakash, Dr. Satya Prakash (collectively "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") against the University of Texas ("UT"), the University of Texas Medical Branch ("UTMB") and multiple individuals from UT and UTMB. The genesis of this matter relates to a botched and dare I say, maliciously handled inquiry into a mistake by Dr. Yoon that has been conducted by Dr. Nisha Garg ("Dr. Garg"), the Scientific Integrity Officer ("SIO") of UTMB. Dr. Garg's malicious efforts have been supported and countenanced by UTMB's legal department and UTMB President Raimer.

This investigation relates to a supplemental figure in a paper published by Drs. Prakash and Dr. Yoon in Genes & Development in 2019. While revising the paper during the publication process, a supplemental figure was added to the paper that did not contain the correct gels. This supplemental figure was not material to the findings, conclusions or results of the paper. When this mistake was pointed out to Drs. Prakash and Dr. Yoon in September 2019, it was immediately corrected and a corrigendum was published by the journal. It is important to note that the publishing journal had no issue with the correction and the paper was not retracted. Additionally, Drs. Prakash and Dr. Yoon implemented procedures to ensure such a mistake would not occur again in the future. This should have ended this matter. Unfortunately, Dr. Garg and others at UTMB had only begun their two-year malevolent process.

Between September and November, 2019 Dr. Garg was made aware in multiple letters of the corrigendum and the changes made in the handling of data going forward in the laboratory of Drs. Prakash. Dr. Garg was also made aware that the mistake was an honest one by Dr. Yoon. However, it is clear from the written record that Dr. Garg either ignored the letters sent to her or did not read them. Instead, Dr. Garg met with the Scientific Investigation Committee ("SIC") to



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investigate Drs. Prakash and Dr. Yoon. The committee met in December, 2019 and in January, 2020 prepared and sent to Dr. Garg an Investigation Report. The Investigation Report called for Dr. Yoon to be terminated immediately. What is interesting is that the Investigation Report also stated that changes were to be made in handling of data in Drs. Prakash's lab, changes that had been implemented months before the SIC met and detailed in the aforementioned letters. This suggests that Dr. Garg failed to provide the written communications containing the exculpatory information provided by Drs. Prakash and Dr. Yoon to Dr. Garg between September and November, 2019 to the SIC, which met in December 2019.

The report was provided to Drs. Prakash and Dr. Yoon in February, 2020. In response, in March, 2020 Drs. Prakash and Dr. Yoon sent Dr. Garg a letter setting forth that Dr. Garg's "investigation" had violated the UTMB' Policy and Procedure Manual of Integrity in Research ("PPMIR"). Our subsequent review has also determined that she also violated multiple sections of 42 CFR § part 93 and the UT Regents Code of Conduct. These include, at a minimum, 42 CFR §93.301(b)(2), 42 CFR §93.302(a)(2)(i – ii), 42 CFR §93.304(b, e and f), 42 CFR §93.305(b), 42 CFR §93.307(a)(1 – 3), 42 CFR §93.307(d)(1 – 2), and 42 CFR §93.307(e – g) and Regents Rules of Conduct Rule 30103 and 30602. The latter violations were identified and pointed out to Dr. Garg, UTMB's legal department and President Raimer on July 26, 2021 and September 16, 2021. To date none of the aforementioned individuals or departments has taken any action to remedy this situation

After sending the March, 2020 letter Drs. Prakash and Dr. Yoon did not hear from Dr. Garg for a year. Then in March, 2021 Dr. Garg sent an email asking Dr. Louise Prakash to confirm that she had fired Dr. Yoon. Drs. Prakash responded a couple of days later stating that they found Dr. Garg's email "perplexing" and pointed out how surprised they were that Dr. Garg had ignored the issues with her investigation detailed in their March, 2020 letter. It was about two and half months later that Dr. Garg wrote to Drs. Prakash and Dr. Yoon that she realized that a mistake had been made in labelling the report by the SIC an "Investigation Report." Dr. Garg then wrote that the "Investigation Report" would now be called an "Inquiry Report," with the only difference being that she had taken out Section 4, which called for Dr. Yoon to be fired. This "Inquiry Report" was sent to UTMB President Raimer who approved the implementation of a formal investigation of Dr. Yoon.

What happened here is flawed in so many ways. First, the process followed by Dr. Garg and UTMB President Raimer still continued to violate the inquiry process set forth in the UTMB PPMIR, several sections of 42 CFR part 93, and the Regents Rules of Conduct. Next, it does not take a genius to determine that removing the conclusion from the original "Investigation Report" and relabeling it an "Inquiry Report" creates an inherent conflict of interest. Either Dr. Garg's investigation finds Dr. Yoon guilty and declares he should be fired, so that the investigation process reasonably appears to have come to a preordained conclusion, or Dr. Yoon is found rightfully innocent and Dr. Garg, UTMB's legal department and UTMB President Raimer have put Dr. Yoon as well as Drs. Prakash through an unwarranted and malicious two-year hell period, with the damage it created. Amazingly, as of the date of this letter neither Dr. Garg,



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UTMB's legal department, or UTMB President Raimer have conceded this conflict of interest even after it was pointed out to them.

So continuing the hell-scape drama, at the end of June, Dr. Garg let Drs. Prakash and Dr. Yoon know that the investigation of Dr. Yoon was now official per the decision of UTMB President Raimer and that Drs. Prakash were to produce papers and grants for the last five years that included Dr. Yoon. At this point, I intervened on behalf of Drs. Prakash and Dr. Yoon and sent Dr. Garg a long letter on July 26, 2021 detailing all of the issues with the handling of this matter by her, UTMB's Legal Department (e.g. Carolee A. King) and President Raimer. I included the aforementioned correspondence as attachments to that letter. I have attached my July 26, 2021 letter with its attachments to the email. It was not until September 2, 2021 that Dr. Garg responded to my letter. In her letter she ignored everything I had stated about her failures to follow the PPMIR and her violations of the UT Regents Code of Conduct. She stated that the investigation would continue under her direction.

At this point it was clear that it did not matter to Dr. Garg or anyone at UTMB that the process they were following violated UTMB's PPMIR, several sections of 42 CFR part 93 and the UT Regents Code of Conduct. Knowing that my clients could not receive fair treatment at UTMB and that everyone from UTMB President Raimer and UTMB's Legal Department on down were biased, prejudiced and clearly did not care that they were causing Drs. Prakash and Dr. Yoon great harm and cognizable damage, I then reached out to Ana Vieira Ayala, Assistant General Counsel in the UT General Counsel's Office on September 10, 2021. I left Ms. Ayala a voice mail asking her to call me as I wanted to discuss serious issues related to my clients at UTMB. Though I did not explicitly state that I was making the call as a Whistle Blower, I fully expected that she would call me back so I could discuss this matter with her. I also reasonably believed that Ms. Ayala understood and appreciated that my message constituted one by a Whistle Blower. Instead, Ms. Ayala contacted Ms. Bremond who heads UTMB's litigation group. I was and continued to be surprised that Ms. Ayala took this step without calling me first to find out why I had called. It has had the effect of "outing the Whistle Blower" and making matters worse for Drs. Prakash and Dr. Yoon at UTMB.

So, Ms. Bremond called me on September 10, 2021 and was impatient and generally pretty nasty. I also believe that she lied to me during the call about her knowledge of the matter regarding Drs. Prakash and Dr. Yoon. After my call with Ms. Bremond, I expected to hear back from her within a few days that Dr. Garg was no longer running the investigation. Surprisingly, I have heard nothing. This prompted me on September 16, 2021 to send Ms. Bremond an email stating that my clients had reached the end of their rope and that this entire process had to end or my clients would have to take any legal and administrative actions available to them. As of today, I still have heard nothing from Ms. Bremond or anyone else at UTMB.

So this brings me to the reason I have sent this letter to you. It is clear to me that there is no means of receiving a fair and nonprejudicial resolution to this matter with anyone at UTMB. In our eyes they are all corrupted. Thus, I am sending this letter to you in a last hope to resolve this



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matter short of litigation. It is my hope that you can intervene in this matter and put things right. That would mean at a minimum, immediately moving this matter out of UTMB and reasonably closing it expeditiously following an unbiased, nonprejudicial review of the facts. Anything less is unacceptable to Drs. Prakash and Dr. Yoon. In the end, Drs. Prakash and Dr. Yoon have suffered great emotional, physical, reputational and other damages; including, this whole malicious matter having a negative effect on their ability to conduct their research. It is our hope that you can end their suffering.

As a courtesy, I have attached the correspondence and the Investigation Report to this letter for your review if you do not already have them. I look forward to your prompt reply and if necessary, I am available to meet you in person to resolve this matter.

Best regards,

Peter D. Weinstein

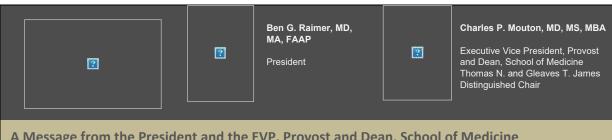
Enclosures

Exhibit B

Subject: A Message from the President and the EVP, Provost and Dean, SOM

Date: Thursday, October 14, 2021 4:32:54 PM

Attachments: image001.png



A Message from the President and the EVP, Provost and Dean, School of Medicine

Oct. 14, 2021

We are pleased to share that David W. Niesel, PhD, will serve as Scientific Integrity Officer (SIO) effective Oct. 15, 2021. As SIO, he will have primary responsibility for adherence to the institution's policies and procedures on research misconduct.

Dr. Niesel has been a leader in UTMB's Research Enterprise for many years. He joined UTMB in 1983 and held leadership roles, including Chief Research Officer and Dean of the Graduate School of Biomedical Sciences, and was a Professor in the Department of Microbiology and Immunology. He retired in January 2021 and has continued to serve as an adjunct faculty member in Microbiology and Immunology.

We are confident in Dr. Niesel's leadership, and we appreciate his service in this extremely important role. Thanks also to Nisha Garg, PhD, for her past service as SIO.

Sincerely yours,

Ben G. Raimer, MD, MA, FAAP President

Charles P. Mouton, MD, MS, MBA Executive Vice President, Provost and Dean, School of Medicine

Thomas N. and Gleaves T. James Distinguished Chair

Exhibit C



Department of Legal Affairs

Carolanda Bremond Woodgett, Associate Vice President Direct Dial: 409-747-8735 Fax: 409-747-8741

cabremon@utmb.edu

October 11, 2021

VIA E-MAIL

Peter D. Weinstein, PhD, JD Managing Partner Entralta P.C. 4500 Williams Drive Suite 212, PMB 511 Georgetown, TX 78633

Re: Louise Prakash, PhD, Satya Prakash, PhD, and Jung-Hoon Yoon, PhD

Dear Mr. Weinstein:

This correspondence is in response to our September 10, 2021 conversation as well as your September 16, 2021 correspondence. As you were previously advised, The University of Texas Medical Branch at Galveston ("UTMB") is a recipient of Public Health Service ("PHS") funds under 42 CFR Parts 50 and 93. Accordingly, UTMB has an "affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work and has primary responsibility for responding to and reporting allegations of research misconduct."

During our September 10, 2021 conversation, you acknowledged UTMB's obligation to conduct an inquiry into the reported actions of your clients, Louise Prakash, PhD ("Prakash"), Satya Prakash, PhD ("Prakash"), and Jung-Hoon Yoon, PhD ("Yoon") as required by the Office of Research Integrity's Division of Investigative Oversight. However, you requested that UTMB engage an independent party to conduct the investigation.

Since we last spoke, UTMB has appointed David W. Niesel, PhD as its Scientific Integrity Officer effective October 5, 2021. Dr. Niesel joined the faculty at UTMB in the Department of Microbiology and Immunology in 1983 and became the Department Chairman. In 1997, Dr. Niesel became the Vice Dean of UTMB's Graduate School of Biomedical Sciences. Thereafter, he was appointed as Vice President and Dean of UTMB's Graduate School of Biomedical Sciences and later Senior Vice President and Chief Research Officer. He assumed the Associate Chief Research Officer position in September 2018 and served in that role until his

Mr. Weinstein October 11, 2021 Page **2** of **2**

retirement from UTMB in January 2021. Since January 2021, he has served as a part-time adjunct professor in the Graduate School of Biomedical Sciences.

In addition, UTMB has requested the assistance of The University of Texas System's Vice Chancellor and General Counsel Daniel H. Sharphorn, JD. Specifically, Mr. Sharphorn has been asked to provide Dr. Niesel and the UTMB scientific integrity program staff with advice and counsel on relevant federal research integrity regulations and guidelines including, but not limited to, 42 C.F.R. Part 93.

With these changes in place, Dr. Niesel will re-initiate the research misconduct review process, beginning with the assessment and inquiry phases as you requested during our September 10, 2021 conversation. As such, the previous January 2, 2020 investigation report will be disregarded. Upon completion of the assessment, Dr. Niesel may be in touch with your client, Dr. Yoon, to initiate the inquiry phase. Please note that if this matter proceeds to the inquiry phase, Dr. Yoon's cooperation as the Respondent and Drs. Prakashs' cooperation as witnesses are a condition of their continued employment. Specifically, as you were previously advised, UTMB's Policy and Procedure Manual on Integrity in Research states, "Institutional members will cooperate with the [Scientific Integrity Officer] and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the SIO or other institutional officials." Furthermore, such failure or refusal will require reporting to ORI and the National Institutes of Health, the funding agency of the grants, for additional action.

I hope this correspondence addresses your immediate concerns.

Very truly yours,

CBWoodgett

Carolanda Bremond Woodgett

CB/mc

Exhibit D





The University of Texas Medical Branch SCHOOL OF MEDICINE

September 2, 2021

Peter Weinstein Entralta P.C., a Litigation, Intellectual Property and Business Law Firm 4500 Williams Drive, Suite 212, PMB 511 Georgetown, TX 78633 P: 805-444-7865, E: peter.weinstein@entralta.com

Dear Mr. Weinstein,

We are in receipt of your letter dated July 26, 2021 (the "Letter"). As a recipient of Public Health Service ("PHS") funds under 42 CFR Parts 50 and 93, The University of Texas Medical Branch at Galveston ("UTMB") has an "affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and has primary responsibility for responding to and reporting allegations of research misconduct". UTMB has been in communication with the Office of Research Integrity ("ORI"), which oversees scientific integrity on behalf of the Secretary of Health and Human Services, and has been advised by ORI's Division of Investigative Oversight ("DIO") to proceed with the investigation into Dr. Yoon by treating the mislabeled "Investigation Report" dated January 2, 2020 as an "Inquiry Report" and disregarding the recommendations contained therein as premature. Your client, Dr. Jung-Hoon Yoon was made aware of these details in a letter dated June 3, 2021. As a result, at this time, the inquiry phase has been completed. On or about June 28, 2021, Dr. Yoon received a copy of a letter dated June 16, 2021, notifying him of UTMB President, ad interim Ben G. Raimer, M.D.'s decision to authorize the investigation and appoint an investigation committee. The investigation committee has made no findings regarding whether or not research misconduct occurred, nor has it made recommendations for institutional actions. As part of the investigation, all three of your clients, Dr. Yoon, Dr. Louise Prakash, and Dr. Satya Prakash will be interviewed and have an opportunity to provide exculpatory evidence.

Currently, UTMB requests the last five years of Dr. Louise and Satya Prakash's lab notebooks and copies of unfunded grant proposals that Dr. Yoon contributed to. This request is a result of a DIO recommendation that UTMB review additional papers, presentations, and grants to which Dr. Yoon may have contributed. In your Letter, you intimated that your clients would not be participating in requests for such information. Please note that cooperation with the conduct of investigations is a requirement of UTMB's Policy and Procedure Manual on Integrity in Research, which states, "Institutional members will cooperate with the [Scientific Integrity Officer] and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the SIO or other institutional officials." Failure or refusal to cooperate with an official UTMB process could affect Dr. Yoon's employment status and Dr. Louise and Satya Prakash's memorandums of appointment. Furthermore, such failure or refusal will require reporting to ORI and the National Institutes of Health, the funding agency of the grants, for additional action.

Sincerely,

Nisha Jain Garg PhD MBA Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston TX

P: 409-747-6865; E: nigarg@utmb.edu

1

¹ Section 93.100 of 42 CFR Parts 50 and 93



Satya Prakash, PhD, Professor, Biochemistry and Molecular Biology, UTMB Galveston Louise Prakash, PhD, Professor, Biochemistry and Molecular Biology, UTMB Galveston Jung-Hoon Yoon, PhD, Biochemistry and Molecular Biology, UTMB Galveston Carolee A. King, JD, Senior Vice President & General Counsel, UTMB Galveston

Exhibit E



Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D. Phone: 805-444-7865 Fax: 805-322-4469

July 26, 2021

Nisha Jain Garg, Ph.D., MBA Scientific Integrity Officer Professor, Microbiology and Immunology University of Texas Medical Branch, Galveston O: 409-7476865

E: nigarg@utmb.edu

RE: Response to Investigation of Drs. Louise, Satya Prakash and Dr. Jung-Hoon Yoon

Dear Dr. Garg,

I have been engaged by Drs. Louise and Satya Prakash (individually, "Dr. L. Prakash" and "Dr. S. Prakash" and collectively, the "Drs. Prakash") and Dr. Jung-Hoon Yoon ("Dr. Yoon") to represent them regarding the investigation undertaken by you on behalf of the University of Texas Medical Branch, Galveston ("UTMB") as UTMB's Scientific Integrity Officer ("SIO") regarding the genesis of Supplementary Figure 2 ("Figure S2") that was published in Genes & Development 33:282 – 287 (2019) (the "G & D paper").

I understand that your investigation started based on a complaint filed by a former member of the Prakash lab group who worked with Drs. Prakash. This complaint was filed with you as SIO in May 2019 and claimed that Figure S2 did not include the right gels.

I also understand that upon learning of the mistake regarding Figure S2 on or about September 2019, Dr. Yoon reran the experiments and then took the new gels to create a substitute Figure S2. This substitute Figure S2 was sent to G & D to be published as a Corrigendum. I understand that the substitute Figure S2 was accepted and published as a Corrigendum by G & D. I understand that the inclusion of Figure S2 did not affect the findings and conclusions of the G & D paper. Indeed, it is my understanding that the papers findings and conclusions would have been the same without Figure S2. Thus, Figure S2 was not material.

As stated earlier, it is not contested that Figure S2 was not material to the findings and conclusions of the G & D paper. Thus, one element that is missing regarding a misconduct

Response to SIO Investigation 7/26/2021

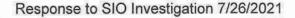


claim is intent. Indeed, Dr. L. Prakash and Dr. S. Prakash have about five decades of outstanding published research and are considered leaders in their field. Dr. Yoon has worked for them for about sixteen (16) years, with many highly regarded publications and no issues regarding his credibility or competence. Thus, there is no past pattern of misconduct by any of these three scientists. What these facts suggest is an honest mistake.

At the outset I must state that I am amazed and stupefied at how you as the SIO have handled this matter to date. As will be detailed below, from the very beginning of the process, you have failed to follow the procedures and rules set forth in UTMB's Policy and Procedure Manual on Integrity in Research ("PPMIR"). The PPMIR sets forth in simple language how you, as SIO, were to handle this matter. What makes this more perplexing is that you as SIO are charged with the knowledge of the procedures set forth in the PPMIR. Despite the clear requirement of you as SIO to know the procedures to handle a complaint about alleged misconduct, you failed to follow them not once, but now twice. Based on your failures and those of the Scientific Integrity Committee ("SIC"), Dr. Yoon, Dr. L. Prakash and S. Prakash have suffered greatly and continue to suffer.

Now as stated in their letter to you dated March 3, 2020, that was signed by Dr. L. Prakash. Dr. S. Prakash and Dr. Yoon, the PPMIR lays out specific steps that are to be followed by the SIO in conducting an inquiry that may lead to an investigation. As you are in possession of the March 3, 2020, letter, which I attach hereto as Exhibit A, I will not reiterate what has already been clearly laid out for you. However, I will state that before you were to start an investigation, you were to conduct an inquiry. At the end of the inquiry, you were to prepare a report as detailed very clearly in the PPMIR on page 10. These elements include (i) a summary of the inquiry process used; (ii) a list of the research records reviewed; (iii) the basis for recommending or not recommending that the allegations warrant an investigation; and (iv) any comments on the draft report by the Respondent or Complainant. Then when you created an inquiry report, you were to provide the findings of the inquiry to Drs. Prakash and Dr. Yoon and allow them to provide their written comments on the findings. Then and only then, you could provide the President of UTMB a copy of the inquiry report. But in doing so, you were also to provide to the President of UTMB the comments from Drs. Prakash and Dr. Yoon. As you are well aware, that is not what happened in the Fall of 2019.

The power to launch an investigation is vested solely in the President of UTMB. Only the President has the power to grant the right to start an investigation, *NOT* the SIO. Additionally, only if the President decides that an investigation is warranted can the SIO provide ORI with the President's written decision, as well as a copy of the inquiry report. Instead of following the clearly defined and simply stated PPMIR procedure, you took it upon yourself to launch in your words an "Investigation" of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. This started in September 2019, four months after the original complaint was filed. You then convened an SIC meeting in December 2019 to determine their guilt. Here again you failed to comply with UTMB's rules set forth in the PPMIR, which clearly state that the investigation committee is to





be formed only after the President of UTMB provides his written approval to start the investigation. Regarding the investigation committee, each of the individuals chosen was to be approved by Drs. Prakash and Dr. Yoon to ensure there was no conflict that would result in a prejudiced decision. Instead, you established an SIC without notifying Drs. Prakash and Dr. Yoon. You then compounded your mistake by failing to provide Drs. Prakash and Dr. Yoon an opportunity to review the SIC member list to provide their feedback and ensure there were no conflicts.

In November 2019, prior to the SIC meeting in December 2019, each of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon sent you a letter. (*see*, Exhibits B – D attached hereto). In these letters, you were provided a reasonable explanation how the error which led to the original Figure S2 occurred. Just as important, you were provided in great detail the measures undertaken by Dr. L. Prakash and Dr. Yoon to ensure a similar mistake *could not occur again*. It is clear by what happened next that you either did not read their letters or you ignored them. What is clear is that you never spoke with any of Drs. Prakash or Dr. Yoon about their letters that were sent to you, the SIO. I also reasonably believe that they were never provided to the President of UTMB or the SIC.

So, you continued your Investigation (your word at the time) and held the SIC meeting in December 2019 where a *judgment* was rendered. Dr. Yoon was to be fired. This was summarized in the "INVESTIGATION REPORT" of January 2, 2020, which is attached hereto as Exhibit E. It is clear from your INVESTIGATION REPORT that you did not read the letters from Drs. Prakash and Dr. Yoon. (*see*, Exhibits B – D). If you had, then the SIC would not have stated as a recommendation on page 3 of your INVESTIGATION REPORT – Recommendations of the SIC.

"that the Department Chair "evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis."

As stated, a process to ensure a similar mistake would not occur had already been implemented and was laid out for you *clearly* in the November 13, 2019, letter from Dr. Yoon. (*see*, Exhibit D). The fact that the SIC is not aware of the implementation of this procedure by Drs. Prakash's lab, clearly shows that you as SIO failed to provide them this critical information prior to the December 2019 SIC investigation meeting.

With the verdict from your investigation in hand, you pass on the verdict from your SIC to Drs. Prakash and Dr. Yoon on February 6, 2020. However, as you should know from the PPMIR, it is the President who decides on the appropriate action to be taken and only after the President determines that the findings substantiate the allegation of research misconduct. As is clear, you as SIO and the SIC had no legal basis to render such a verdict. In rendering a final judgment, you and the SIC *violated* the UTMB PPMIR and as a result you and the SIC caused and continue to cause great harm to Drs. Prakash and Dr. Yoon.





Now for reasons I do not understand, after Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon sent you their March 3, 2020, letter (*see*, Exhibit A) that laid out in detail all of your mistakes regarding the process set forth in the UTMB PPMIR and other issues with the verdict, you did not respond. Indeed, Drs. Prakash and Dr. Yoon did not hear from you again for almost a year when you sent an email to Dr. L. Prakash, as well as Valerie Rosemond and Carolee King, both of UTMB on March 23, 2021. (*see*, Exhibit F attached hereto). In your email, you stated that you had been asked by the Office of Research Integrity if the administrative actions, meaning the verdict rendered by the SIC in the INVESTIGATION REPORT, had been implemented. You then required that Dr. L. Prakash respond to you by March 29, 2021, with the answer.

On March 25, 2021, Drs. L. and S. Prakash responded. (*see*, Exhibit G). They pointed out to you that it was "perplexing" that you had ignored their March 3, 2020, letter, where you were informed in great detail that you *failed* to follow the UTMB PPMIR and *violated* their rights. If you, the SIO, had paid attention to their March 3, 2020, letter, at minimum, you ought to have realized right then that you and the SIC had made a grave error in having informed ORI. It was incumbent upon you at that time to have informed ORI that you had failed to follow the *required* steps of an inquiry under the UTMB PPMIR. You should have informed the ORI that you and the SIC failed to handle this matter properly. Then, you should have withdrawn the report from ORI and apologized to the ORI for your serious mistake. Of course, you and the SIC failed to undertake any of these required steps. As a result, the entire tainted process you pursued and the submission of the report to ORI were illegal, unwarranted, reckless, and extremely damaging to Dr. Yoon and Drs. Prakash.

As you should be well aware, your standard regarding how Dr. Yoon is to be treated for a single honest mistake must be applied to you as SIO and the SIC. Indeed, I would expect that you would agree that you as SIO should not receive preferential or better treatment than Dr. Yoon. Particularly, where you as SIO are charged with knowing the procedures and rules to be followed pursuant to the UTMB PPMIR. Indeed, your failure should be considered worse than Dr. Yoon's honest mistake. As under your own rules there are no do overs, I will continue to call the inquisition you launched and continue to prosecute an Investigation. I will also continue to call the January 2, 2020, verdict, the INVESTIGATION REPORT.

However, I do agree with that part of your statement that the SIC did not find any research misconduct by Dr. L. Prakash or Sr. S. Prakash. I also believe that based on this correct finding, that it was right to close the case against Drs. Prakash. I also understand that the NIH Office of Research Integrity ("ORI") came to the same conclusion in a letter sent to you on June 21, 2021, from Alexander Runko, Director, Division of Investigative Oversight, ORI. (see, Exhibit H attached hereto).

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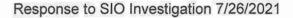
Next, I understand that you sent the INVESTIGATION REPORT to President Ben G. Raimer to request permission to start an investigation into Dr. Yoon. In doing this, you once again failed to allow Dr. Yoon to provide comments for President Raimer to assist in his decision. You also failed to interview Dr. Yoon or Drs. Prakash. So now for a second time, you failed to follow the procedures and rules set forth in the UTMB PPMIR. As you should be able to imagine, this is amazing and perplexing all in one. You were informed of your violation of UTMB's PPMIR almost a year and a half ago. You acknowledge in your discussions with the Director of ORI (your June 3, 2021, letter to the respondents) that you had made a mistake in labeling the SIC Report as an Investigation Report. It can only be assumed that this was based on the information provided by Drs. Prakash and Dr. Yoon. So, the SIO who wants Dr. Yoon fired for a single honest mistake continues to make mistake after mistake, even after being informed of her mistakes.

However, you received the result you wanted. You were able to intentionally mislead President Raimer and obtain his approval of an investigation into Dr. Yoon by gaming the system. You failed to inform President Raimer of your repeated failures to follow the rules as set forth in the UTMB PPMIR. The irony is that your compounded failures fail the standard of what one would hope for regarding a Scientific Integrity Officer of UTMB who is charged with upholding the school's standard of "Integrity."

With President Raimer's improperly attained approval in hand, you next requested that Dr. L. Prakash send you a list of Dr. Yoon's publications over the last five (5) years, which she did. And now, you are continuing your fishing expedition by asking for Drs. Prakash to send you the last five (5) years of their grant applications. To this, I say no on behalf of Drs. Prakash and Dr. Yoon. This inquisition needs to end and if there is an accounting to be had, it is of your incompetent and malevolent conduct and behavior as SIO in this affair. Indeed, it raises the serious question whether the SIO should be the one who is fired.

As stated previously, as SIO you are to follow very specific and simple rules and procedures on how to conduct an inquiry. Then, if reasonable and necessary, and following President Raimer's approval, you can conduct an investigation following the procedures set forth in UTMB's PMIR. You failed in this simple task, not once, but again after having your first failure pointed out to you. You continue to prosecute your inquisition, while failing to follow your own rules.

Further, throughout your inquisition, you have failed to provide an answer to a key component of the inquiry. Why would Dr. Yoon have intentionally created a false Figure S2 if it was not material. Particularly, when he has no history of falsifying data. You never obtained this answer because you never interviewed him on this specific point. If you had, you would have learned it was an honest mistake due to the pressure of working on multiple things at once on his computer as he stated in his November 13, 2019, letter to you. (*see*, Exhibit D). I would doubt that you or someone working in your lab has not or could not have made a similar mistake under the same circumstances.





Thus, based on the facts in this matter, it is clear that if there is to be an investigation, it should be of you and your conduct as SIO. You have tortured Drs. Prakash and particularly, Dr. Yoon for almost two (2) years with your inquisition for a simple non-material and honest mistake. You have caused each of them great physical, emotional and mental harm and whether you realize it, professional harm. You have done this despite Dr. Yoon letting you know of the great emotional, mental and physical toll your inquisition has taken on him personally. It is clear you do not care for their wellbeing.

Now your behavior and conduct as SIO raises serious legal and administrative issues. This includes your violation of Regents Rules of Conduct, Rule 30103. This rule explicitly states that any employee who, acting singly or in concert with others, obstructs, disrupts, or interferes with any research or other activity authorized to be held or conducted on campus or on property or in a building or facility owned or controlled by The University of Texas System or any of the institutions is subject to disciplinary action, including dismissal. It goes without saying that your willful inquisition, which has not followed the explicit rules and procedures set forth in the UTMB PPMIR has clearly disrupted the research and other activities of Dr. L. Prakash, Dr. S. Prakash, and particularly, Dr. Yoon.

But your violations of the Regents Rules of Conduct do not stop there. Rule 30602 states that

"it is the policy of the University of Texas system or any of the institutions to encourage, fair, efficient, and equitable solutions for problems arising out of the employment relationship and to meet the requirements of State and Federal law."

It goes without saying that the inquisition that you have pursued against Drs. Prakash and Dr. Yoon has not been fair, efficient or resulted in an equitable solution. Instead, it has been wholly unfair, unreasonable, inefficient and just cruel. Particularly, when you consider the improper and illegal judgment of you as SIO and the SIC in the INVESTIGATION REPORT that Dr. Yoon be fired after 16 years of outstanding service for a non-material and honest mistake. In what universe can this be reasonably considered as an equitable solution. Your inquisition has caused Dr. Yoon great mental and physical anguish. It has resulted in serious emotional trauma.

Thus, it goes without saying that your actions over the last two (2) years as SIO of UTMB have resulted in cognizable and significant damage to each of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. So here is what we expect to happen to close this matter. You will provide a letter to Dr. Yoon stating that there is "no evidence" of misconduct by him. This will be shared with President Raimer, the ORI and each member of the SIC. Then you will close this matter.

Failure to take this reasonable step and end this charade will require Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon to consider the legal and administrative remedies available to them. As I am sure you are aware, these include obtaining legal redress for the cognizable harm they have suffered from the actions you as an individual have taken against them personally (clear federal civil rights violations), UTMB and the members of the SIC. It will also include filing a complaint



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against you personally as SIO of UTMB with the General Counsel's Office of the University of Texas system for your actions and continued and knowing violation of the Regents Rules of Conduct and UTMB's PPMIR to the significant detriment of Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon. Other administrative remedies will also be considered.

This whole inquisition should have been terminated following your receipt of the letters from Dr. L. Prakash, Dr. S. Prakash and Dr. Yoon in November 2019. By then the non-material and honest mistake had been corrected and procedures had already been implemented to ensure it would not happen again. But you decided to press your inquisition to the significant detriment of everyone, including UTMB and President Raimer. I expect that this will end now.

Sincerely,

Peter D. Weinstein, Ph.D., J.D.

Managing Partner

Response to SIO Investigation 7/26/2021

EXHIBIT A



6.104 Medical Research Building 301 University Boulevard Galveston, TX 77555-1061 O 409.747.8601

March 3, 2020

Dear Dr. Garg:

This letter is in response to the Investigation Reports you sent to each of us, the Respondents, Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.-H. Y) on Feb. 6, 2020 at 4:14 PM, in which you reproduce the allegations made by the complainant of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our Genes & Development publication, vol. 33, 282-287, 2019. These letters list the members of the UTMB standing SIC involved in both the Inquiry and Investigation and the Summary Statement and Recommendations of the SIC. Given serious issues with the process and significant concerns about the content of this investigation, we object to the recommendations proposed in it, namely dismissal of Dr. Jung-Hoon Yoon from UTMB.

Let me start with our serious concerns about the process. The guidelines of the Policy and Procedure Manual on Integrity in Research (PPMIR) are very clear on the steps that need to be taken in determining the merit of allegations of misconduct; however, as documented below, the proper procedures were not adhered to in this particular case.

Since the guidelines indicate that an inquiry report, which we have not seen and suspect does not exist, should have been sent to the President, we have copied him on this communication; and since we have discussed this matter with the Chair of our Department, we have copied Dr. Mariano Garcia-Blanco as well.

Page 7, section IV E of the PPMIR, states: "During the research misconduct proceeding, the SIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for by law and UTMB policies and procedures."

We did not receive any notices during the proceedings

We list below specific examples where proper procedures were not followed, along with our comments noted in bold:

- (1) Section VI A p.10 of the PPMIR details what the written Inquiry report should contain. Among other items, it should include a summary of the inquiry process used, a list of the research records reviewed, the basis of concluding whether or not an investigation is warranted, and any comments on the draft report by the Respondent or Complainant.
 - We were not provided with any such information and were given no opportunity to comment on the inquiry report.
- (2) Section VI B on p. 10 of the PPMIR states that the SIO shall provide a copy of the inquiry report to the President and to the respondent at the same time and that the respondent has 10 calendar days to send comments to the President regarding the contents of the inquiry report.
 - We were never given a copy of the inquiry report; therefore, we were not allowed the opportunity to send our comments to the President.

- (3) On p. 11 in section VI B of the PPMIR, it states that "The President will determine in writing whether an investigation is warranted."
 - The letters we received from you on Feb. 6, 2020 were entitled "INVESTIGATION REPORT" and state that the SIC members determined there was sufficient ground to proceed to the investigation step. This implies that several steps in the mandated process were not carried out according to the guidelines set forth in PPMIR.
- (4) Once the President has determined that an investigation is warranted, in section VII C, p. 12 of the PPMIR, it states that "The President, in consultation with the SIO and other institutional officials as appropriate, will appoint an investigation committee of at least 3 members..." Thus, the SIC and the Investigation Committee are NOT the same.
 - The bottom of page 1 of the letters we received from you lists the names, etc. of the UTMB SIC members involved in BOTH the inquiry AND the investigation.
- (5) On p. 12, in section VII C of the PPMIR, it states that "The President will notify the Respondent of the proposed committee membership to give the Respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest."
 - We never received any such notification. In fact, as noted above, the SIC committee performed both the inquiry and investigation reports whereas in the email of Sept. 17, 2019 at 1:25 PM, we were notified that it was an inquiry which you would like to complete in 60 days.
- (6) According to p. 13, section VII E of the PPMIR, the investigation committee and the SIO must interview each Respondent and Complainant.
 - None of us, the respondents, were interviewed by the Investigation Committee.
- (7) Section VIII. A on p. 14 provides a list of the elements that the written draft of the investigation report needs to include.
 - No details were provided in the investigation report.

The SIC's actions are even more troublesome in view of the fact that we had provided all the information we were asked for, as noted below.

Your email of Sept. 17, 2019 at 1:25 PM stated that "We would like to complete the inquiry in the next 60 days". In a later email that day (Sept. 17, 2019 at 3:28 PM) you wrote "Please provide us, in defense, documentation for the ability to detect endogenous level of Rev1, DNA Polymerase lota, DNA polymerase kappa in human or other cells used in the study, and original Western blots / images of the original blots, and documentation of the experiments." We, all 3 respondents: Satya Prakash (SP), Louise Prakash (LP), and Jung-Hoon Yoon (J.H.-Y) provided you with extensive documentation of our ability to carry out these studies in our November 18, 2019 response to you. In addition, we provided the corrigendum for Supplemental Fig. 2 that has been published in Genes & Development. And in our letters (SP & LP), we pointed out the highly error-free track record of Dr. Yoon and we noted that the inclusion of Supplemental Fig. 2 had no bearing on the impact or conclusions of this study.

Between Sept 17 and Nov 18, before we sent you our letters of response, I (LP) communicated with you by telephone several times for advice on what information to include in our response. After

spending many hours examining the complainant's notebooks and comparing relevant pages to the Western Blots (WBs) he referenced, I found many discrepancies which led me to question the validity of his allegations. In the draft of my original response, I had included the following statement: "I want to point out that I spent a lot of time examining the notebooks of the individual making the complaint and I found several instances in which the points brought out by the complainant did not confirm the allegation." We (SP & I) accepted your suggestion to remove this statement because we were given the impression that it was not necessary - thinking that all you needed was the evidence you had asked for in your Sept. 17, 3:28 PM email. Therefore, we were shocked and traumatized to receive your email of February 6 with the attached Investigation Report letters, since we had not been made aware that the Inquiry Phase had progressed to the Investigation Phase.

We (LP & SP) have discussed this situation with our Chair, and respectfully request that the Guidelines of the PPMIR be followed and that the Inquiry and subsequent steps be re-initiated from the beginning. Importantly, I (LP) have uncovered that the majority of the complainant's allegations cannot be substantiated, and it is only if the Inquiry is followed in the proper order that we can discuss these issues with the SIC inquiry committee, and with the Investigation Committee, should it proceed to that stage.

The precipitous action of the SIC and its recommendations, especially the extreme one that Dr. Yoon be terminated from UTMB, without consideration of his excellent track record, path breaking publications, and his devotion to science (for a detailed explanation see our letters that were included in our Nov. 18, 2019 email to you and are attached here) have been extremely devastating to all the respondents. We also feel that no consideration was given to the circumstances under which this error occurred, for which Dr. Yoon has been extremely remorseful, and the steps we have undertaken to avoid such errors in the future (see Section §93.408 Mitigating and aggravating factors in HHS administrative actions, p. 648 of Public Health Service: Policy on Scientific misconduct 42 CFR Part 93).

Content of Allegations

In this communication, we have not addressed in detail the content of the allegations. We will comment on them at the appropriate stage and will do so in great detail.

Thank you very much.

Sincerely,

Louise Prakash

Louise Prakash

Satyr Prakash

Satyr Prakash

Jung-Hoon Yoon



Response to SIO Investigation 7/26/2021

EXHIBIT B



Subject: Genes & Development paper

November 5, 2019

Dear Committee:

At the outset, I categorically state that I had no knowledge of any issues with the western blots (WBs) shown in Supplemental Figure 2 and I was in no way involved in any of the aspects of constructing this figure.

I have worked closely with Hoon since he joined our group in March 2005. In my long academic career, he is one of the very best colleagues that I have worked with. Hoon has high ethical standards; he cares deeply about discovering the truth and reporting the scientific facts, and his impeccable and impressive first author contributions with us over the past 10 years attest to this fact.

I have thought long and hard about how Hoon, who is such a diligent and highly conscientious individual who repeats experiments too many times to assure the accuracy of his data and conclusions, could end up being responsible for mixing up the information assembled in Supplemental Figure 2. Knowing Hoon as a person and as a scientist as well as I do, knowing the difficult circumstances in which this work was being put together, and the fact that he shares all the important aspects of a project with me, regardless of how negatively that may impact the outcome of the study or its publication, and irrespective of the time he has spent on it, I can affirmatively say that there is absolutely no way that this highly distressing episode occurred because it was in any way intentional.

In the original version of the paper submitted to G&D, we had not included Supplemental Figure 2 because the observation that depletions of respective DNA Pols reduce the frequency of translesion synthesis (TLS) opposite1,N6-ethenodeoxyadenosine (ϵ dA) had provided strong genetic evidence for the effectiveness of siRNA depletions and also because we had published such evidence before. Moreover, since in the revised version, we had included the evidence generated in Rev1- $^{1/2}$ and Pol $^{1/2}$ mouse embryonic fibroblasts (MEFs) that a reviewer had asked for, it was not necessary to include a western blot (WB) figure of siRNA depletions,. Even then I decided to include a WB figure of siRNA depletions in the revised version and asked Hoon for such a figure. I believe that this unnecessary and undue burden I put upon Hoon to assemble such a figure in a short time led to errors in compilation of this figure.

Over the years, Hoon has been working almost single-handedly on a number of novel and path-breaking projects and he has been under pressures which he puts upon himself and the pressures that I put upon him. I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion. Clearly, he did not realize the degree of mental exhaustion or the mistakes he was making when he put the figure together. It is impossible for me to see that Hoon, who cares so deeply about the validity of his results and conclusions, would knowingly misrepresent a figure which has little bearing, if any, on the data shown in the paper or on the conclusions drawn. A person with intent to falsify or misrepresent data would do so for aspects which elevate the impact of the study and not something as marginal as this figure.

In reviewing all the past contributions of Hoon with us, I have become deeply aware of the immense amount of information he puts together in preparation for each paper, and of how error-free and meticulous each of his publications is. Nevertheless, to avoid the possibility of any errors in the future, I will help Hoon in verifying the accuracy of each of the items that are included in the paper. I will also make sure that Hoon is not working on a number of different projects at the same time.

Hoon has been traumatized by the fact that he is responsible for this mishap in the figure. He is a highly devoted scientist who cares deeply about the accuracy and biological relevance of his findings and over the years with us, he has been responsible for a number of pioneering studies published in a number of leading journals, including Cell, Genes & Development, PNAS, and others Moreover, Hoon has been working assiduously on a number of other important projects. I strongly believe that publication of these studies will be highly impactful and paradigm shifting for a number of DNA repair genes which play highly effective roles in protection from breast and ovarian cancers and from leukemias.

Sincerely yours,

Satya Prakash, Ph.D.

Satya Pracosh

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology 6.104B Medical Research Building

Telephone: 409-747-8602 e-mail: saprakas@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT C



Subject: Genes & Development paper

November 13, 2019

Dear Committee,

I wish to state at the outset that I was not involved in any way in assembling the data for the gels presented in Supplementary Figure 2. My role was to combine the Supplementary Figure files given to me into one pdf file for submission to the journal, along with the text and text figures.

Both Satya and I were shocked when we learned about the allegation against Dr. Jung-Hoon Yoon, the first author of a manuscript published in Genes & Development in March of this year. It is important to understand the kind of person that Hoon is because then it becomes totally incomprehensible that Hoon could have knowingly and intentionally misrepresented the data in Supplementary Figure 2. He has been with us for the past 14 years, and during that time, I have had ample opportunity to observe the way he conducts himself in his research and how meticulous he is with his data. He is extremely honest, forthright, conscientious, and a most trustworthy, reliable, hardworking, and responsible individual. He always repeats his experiments numerous times to be as sure as one can ever be in science that the data are reproducible and that the conclusions are warranted. The quality and quantity of work that has gone into each of his publications shows that he has accomplished a phenomenal amount of work. He has single-handedly been doing the work that in other labs would be handled by a number of individuals. In fact, one of the reviewers of the recent Cell paper on which Hoon is first author said "This is a monumental work that addresses a key problem in skin cancer and elucidates the roles of Pol0 and other TLS polymerases." (Underline mine). And another reviewer wrote "These data provide unambiguous evidence of skin cancer arising in the absence of UV induced mutations. This is a paradigm-shifting finding as it questions the dogma that UV induced mutations cause skin cancer". In this paper as well as in all his other papers, Hoon has been the prime mover - being responsible for the major aspects of the study.

After going over the details with Hoon it has become clear to me that Hoon was working under tremendous pressure at the time he prepared this figure. He was asked by Satya to provide a figure of western blots showing siRNA knockdowns of the various TLS polymerases used in the study, Hoon made errors because during compilation of a number of western blots, he had many gel images open at the same time, and he picked the wrong images. When Hoon realized what he had done, he was completely devastated. He blamed himself endlessly, and felt strongly that he has brought shame on himself as well as on all others associated with him. It took several days for him to recover sufficiently to be able to address with us the details of how this might have come about. He made a genuine mistake, and I cannot over-emphasize how truly remorseful he has been. This is all because he takes his scientific work very seriously.

I have gone over various ways to reduce the probability of errors arising in the future regarding confusion in identifying western blots or similar types of data. We both agree that annotating each blot with a western blot marker pen such that the date and samples are clearly indicated will be most useful to achieve this end. In addition, applying the same code to the original file

name created by the ImageQuant instrument and to the corresponding blot should avoid any ambiguity as to the identity of the blot. He will also keep a detailed record in a lab notebook where the code name will include an illustrator file of the blot and a legend indicating what is in each lane and the relevant experimental conditions used. From now on, I will carefully go over with Hoon's record keeping in this regard and I am confident that this strategy will serve to avoid mistakes in the future.

We have compiled a new Supplementary Figure 2 and have sent this figure to Genes & Development to be published as a Corrigendum. I have been corresponding with Dr. Laureen Connell, Senior Editor, Genes & Development, regarding the corrigendum and there do not seem to be any issues with replacing the figure. The emails from Dr. Connell are included with the materials provided to the committee.

Thank you for giving us the opportunity to explain the circumstances that led to mistakes in the compilation.

Sincerely yours,

Louise Prakash, Ph.D.

Laure Propost

Professor, Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences Department of Biochemistry and Molecular Biology

6.104A Medical Research Building

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

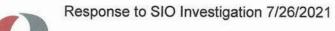




EXHIBIT D



November 13, 2019

Letter of Explanations to Scientific Integrity Committee

In going over Supplementary Figure S2, I have realized that I failed to keep a record of how I had compiled this figure and it has become clear to me that I made errors in assembling this figure. I am always very concerned about the accuracy and repeatability of my data and I have been extremely upset about not being careful in assembling this figure I want to emphasize that all these mistakes are unintentional errors and I wish to explain the circumstances under which this figure was made.

I joined the Prakash lab in 2005 with a specific purpose of studying translesion synthesis (TLS) mechanisms in human cells. For this purpose, I designed a novel duplex plasmid system in which replication through a site-specific DNA lesion present on the leading or the lagging DNA strand could be analyzed methodically. For determining the contribution of various TLS polymerases (Pols), I began using siRNA depletion method as this approach avoids the complications of genetic suppression or other genetic artifacts that accompany null mutations. After over two years of effort, I established the plasmid system and optimized the efficient siRNA depletion conditions for a number of TLS Pols in human and mouse cell lines. To confirm the efficient siRNA depletion of TLS Pols in mammalian cells, I used western blot analysis and if necessary, RT-PCR. The establishment of these approaches has allowed me to systematically analyze the genetic control of TLS opposite different types of DNA lesions in human cells and these studies have been published in prestigious scientific journals.

When I prepared the Figure S2 for the Genes & Development paper, I was working under tremendous pressure of time and of having to deal with a number of different ongoing studies. Moreover, in the last year I had taken over the work of post-docs who had left the laboratory. At the same time, I was handling a rather complex paper for Cell, and when Satya wanted me to provide a new figure for siRNA depletions, because of the concern for the revision deadline, I rushed to finish the figure. I opened many files of western blot images on the computer screen and because of lack of attention and confusion, I mixed up the files and didn't double check the final figure before submission. I do realize that there is no excuse for my making these mistakes; from now on, I will be much more careful so that such mistakes never happen again.

To avoid such errors from occurring in the future, I have discussed a strategy with Louise which I plan to follow. Our laboratory uses the ImageQuant LAS4000 camera system for obtaining digital images of our western blots of other samples. The digital images are produced by exposing the blot to chemiluminescence and the system automatically names the file with the date it is created. From now on, for each file genrated by the ImageQuant, I will add a code name to each corresponding blot using a western blot marker pen so that there will be no ambiguity as to the identity of the samples in a particular blot. In addition to annotating each blot with the date and sample name, I will keep a detailed record of each blot in a notebook where every lane of the particular blot will be clearly labeled as to what sample is in each lane, what antibody was used, and any other pertinent experimental details. Blots will not be copied into adobe illustrator until they have been clearly marked. We expect that this procedure will substantially reduce the probability of error. In addition, I will consult with Louise and show her my annotation system so that there will be no confusion as to what each blot represents.

Thank you very much for considering my explanation of the circumstances that led to this unfortunate, and entirely unintentional, incident for which I take full responsibility.

Sincerely yours,

Jung-Hoon Yoon, PhD

Research Scientist

Biochemistry and Molecular Biology

6.108 Medical Research Building

Telephone: 409-747-8604; e-mail: juyoon@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT E

University of Texas, Medical Branch in Galveston ("UTMB")

Confidential Sensitive

Allegations of Research Misconduct Respondent: Prakash Satya, PhD

Date of SIC Meeting: December 19, 2019

Report Date: January 2, 2020

1. INVESTIGATION REPORT

1.a. Background and summary of Inquiry

In a message dated May 5, 2019, allegations of research misconduct were raised by a complainant. The allegations stated possible research misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019).

Panel A - top left: blot for TLS Pol in NC/Poln samples is from another blot for a different protein.

Panel A - middle left: Polφ data is from another blot for a different protein in different cells, Rev1 blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Poli data are from a blot for another protein.

Panel B- Western blot for Poli and tubulin for NC/Polo samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data. This manuscript cites support from US PHS funds, specifically NIH grants ES022948 and GM126087 (PI: Prakash).

Though the complainant identified Yoon, Jung-Hoon, PhD, Research Scientist in the Department of Biochemistry and Molecular Biology (BMB) as respondent. Dr. Yoon was identified to directly report to Dr. S Prakash. Thus, Dr. S Prakash was also identified as respondent.

Dr. NJ Garg Scientific Integrity Officer (UTMB) met the complainant in May 2019 and received the material justifying the allegation. The material received from complainant is attached as **Appendix 1**.

Dr. Garg (and Ms. Bricker) met Dr. Yoon, Dr. S. Prakash and Dr. L Prakash (identified as respondents) on Sept 16 and Sept 17 to present the allegation. Notebooks and computer hard drive were sequestered on September 16. The Scientific Integrity Committee members determined there is sufficient ground to perform investigation.

The Investigation

1.b. Names, titles and CVs for UTMB SIC members involved in Inquiry and Investigation.

The members of the UTMB standing SIC are listed below. The biosketches of the members are available on request.

Dr. Nisha J Garg, PhD MBA (Professor, Microbiology & Immunology, School of Medicine (SOM) and Scientific Integrity Officer)

Dr. Giulio Tagliatela, PhD (Professor, Neuroscience, SOM and Chair, SIC)

Dr. David H Walker, PhD (Professor, Pathology, SOM)

Dr. Lorraine Evangelista, PhD (Professor, School of Nursing)

Dr. Blake Rasmussen, PhD (Professor, Nutrition and metabolism, School of Health Professions)

Dr. Rebeca Wong, PhD (Professor, Preventive Medicine and Community Health, SOM)

Dr. B Monte Pettitt (Professor, Biochemistry & Molecular Biology, SOM)

Dr. V Suzanne Klimberg (Professor, Surgery, SOM)

Ms. Carolee A King (JD Senior Vice President & General Counsel, ex officio member)

Ms. Kimblyn Raschke / Ms. Nancy Bricker (Administrative support, ex officio)

1.c. Names and titles of all respondents:

Respondent S Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent L Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent Yoon, Research Scientist, Biochemistry and Molecular Biology, UTMB

1.d. Attorneys if relevant: None

1.e. PHS support/ORI jurisdiction.

The following grants funded by NIH were cited in the publication:

Paper Grants

Paper: Genes & Development 33:282-287 (2019) ES022948 and GM126087

2. Investigation process:

Dr. Garg and Ms. Bricker met the respondents on Sept 6-7, 2019 to present the allegation and sequester the relevant notebooks and hard drive.

The respondent L Prakash kept contact with Dr. Garg through emails and phone calls and provided detailed response on November 18, 2019. The statements received from all respondents are attached as **Appendix 2**. Respondent has also provided new data (**Appendix 3**) and communications with the journal (**Appendix 4**).

The collected information and data were sent to the members of the SIC investigation committee electronically on 11/19/2019. Members discussed the case electronically and formally met on December 19, 2019.

The presented report was approved by SIC members by January 25, 2020 and the legal counsel on February 6, 2020.

3. Summary:

Dr. S Prakash (respondent) states, "I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion". Dr. S Prakash (respondent) maintains that it was an honest error of Dr. Yoon.

All respondents could not identify the original gels that were used to submit Figure S2. Lacking that, all experiments/WB for Figure S2 were repeated, and new data were utilized to assemble new Figure S2 (attached as Appendix 3). The newly generated Figure S2 was sent to the G&D journal (Appendix 4). The journal accepted to publish revised version of the Figure S2 as corrigendum.

Scientific Integrity Committee: The person who ran Western blots in the lab has moved to another location. His folders were sequestered and found to be appropriately labeled with all details and needed information. However, the data presented in S2 Figure were found to be cut from images that belonged to data collected with other antibodies. Dr. Yoon was directly involved in assembling the data for publication and he accepted the responsibility for mis-presentation of data. Dr. S Prakash was not identified to have direct knowledge of mis-presentation of data.

SIC members unanimously concluded that falsification and fabrication of data occurred. SIC members considered that a lack of supervision and over-confidence in the capabilities of Dr. Yoon likely resulted in mis-presentation of data. However, SIC members concurred that there is no evidence that suggest that Dr. Prakash had direct knowledge of mis-presentation of data and he was likely not involved in falsification and fabrication of the data presented in Figure S2.

- 4. Recommendations of the SIC: Members of the SIC recommended the following:
 - 1. SIC members request the Chair of the Department to evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis. It will be essential that PI is aware of and has confirmed the accuracy of all raw data to be used for future publications.
 - 2. Notification to the Office of Research Integrity and Federal Funding Agency.
- 5. Notice to the respondent of the institutional decision and administrative action. Pending

Submitted by:

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston

O: 409-747-6865, E: nigarg@utmb.edu

Response to SIO Investigation 7/26/2021



EXHIBIT F

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 343 of 514

From: Garg, Nisha <nigarg@utmb.edu> Sent: Tuesday, March 23, 2021 4:26 PM

To: Prakash, Louise < loprakas@UTMB.EDU>; Prakash, Satya < saprakas@UTMB.EDU>

Cc: Rosemond, Valerie S. <vsrosemo@UTMB.EDU>; King, Carolee A. (Legal) <caaking@UTMB.EDU>

Subject: G&D paper

Hello Louise and Satya. I have been asked by the office of research integrity to address if the administrative actions recommended in Scientific Integrity Committee report are implemented. For this purpose, I request you to let me know the current employment status of Dr. Hoon and the lab procedures/protocols that are implemented/followed to ensure proper recording of the data and gel images in the lab.

Please send your response by Monday March 29th at the latest. Thank you

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer Professor, Microbiology & Immunology University of TX Medical Branch at Galveston O: 409-747-6865; E: nigarg@utmb.edu



Response to SIO Investigation 7/26/2021

EXHIBIT G

Prakash, Louise

From:

Prakash, Louise

Sent:

Thursday, March 25, 2021 2:27 PM

To:

Garg, Nisha

Cc:

Raimer, Ben G.; Garcia-Blanco, Mariano A.; Rosemond, Valerie S.; King, Carolee A. (Legal)

Subject:

RE: G&D paper

Attachments:

Response to Investigation Report letters

Importance:

High

Dear Nisha,

We find your communication of March 23, 2021 (4:26 PM) perplexing because we had sent you an email letter over one year ago, on March 3, 2020, documenting in great detail our serious concerns regarding the allegation of possible misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in our *Genes & Development* publication (2019, vol. 33, 282-287). In addition to sending that email and the attached materials to you, we had copied President Ben Raimer and our Chair, Dr. Mariano Garcia-Blanco. As you will note in that email (which is attached here), we expressed our concerns in detail and cited numerous examples of how procedures described in the <u>Policy and Procedure Manual on Integrity in Research (PPMIR)</u> of the University of Texas Medical Branch at Galveston had not been followed. Since we did not hear from you, we assumed that the matter had been closed. We have discussed this matter again with Dr. Garcia-Blanco and he shares our concerns.

Dr. Yoon's employment status at UTMB remains the same and he continues to make seminal contributions to translesion DNA synthesis mechanisms. Also, we stress that for each experiment we have been following very methodical and stringent procedures to ensure proper recording of the data and gel images.

Sincerely,

Louise Prakash, Ph.D.

Professor, Department of Biochemistry and Molecular Biology
I.H. Kempner Professor in Human Genetics
loprakas@utmb.edu

Satya Prakash, PhD.

Professor, Department of Biochemistry and Molecular Biology Charles Marc Pomerat Professor in Biological Sciences saprakas@utmb.edu Response to SIO Investigation 7/26/2021



EXHIBIT H

DEPARTMENT OF HEALTH & HUMAN SERVICES



Office of the Assistant Secretary for Health Office of Research Integrity 1101 Wootton Parkway, Suite 240 Rockville, MD, 20852

> Phone 240-453-8800 FAX 301-594-0043

Email alexander runko a hhs gov Web https ori dhhs gov

CONFIDENTIAL/SENSITIVE

June 21, 2021

Nisha Jain Garg, Ph.D., MBA Scientific Integrity Officer Professor, Microbiology & Immunology University of Texas Medical Branch 301 University Blvd. Galveston, TX 77555-0342

TRANSMITTED VIA EMAIL TO: nigarg@utmb.edu

RE: ORI 2021-18 (DIO 7323)

Dear Dr. Garg:

The Division of Investigative Oversight (DIO), Office of Research Integrity (ORI), has reviewed the report of the inquiry conducted by the University of Texas Medical Branch in Galveston (UTMB) into allegations of possible research misconduct against Louise Prakash, Ph.D., Professor, Department of Biochemistry and Molecular Biology, UTMB. Dr. Prakash allegedly falsified and/or fabricated data in a supplementary figure in one (1) published paper. The questioned paper cited support from U.S. Public Health Service (PHS) funds, specifically National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES022948 and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM126087.

DIO concurs with UTMB's determination that there is insufficient evidence against Dr. Louise Prakash to warrant proceeding to an investigation. Therefore, DIO has administratively closed this case without further action.

Consistent with Federal law and ORI policy, research misconduct proceedings that result in no PHS finding of misconduct remain confidential for ORI. We ask that you respect this policy. We appreciate your reporting to DIO under 42 C.F.R. § 93.309.

¹Yoon J-H, Johnson RE, Pra kash L, Pra k ash S. DNA polymerase θ accomplishes translesion synthesis opposite 1, N°-ethen odeoxyadenosine with a remarkably high fidelity in human cells. *Genes Dev.* 2019 Mar 1;33(5-6):282-87.

CONFIDENTIAL/SENSITIVE

ORI 2021-18 (DIO 7323)

Page 2

If you have any questions about this matter, please contact me at alexander.runko@hhs.gov or 240-453-8800.

Sincerely,

Alexander P.

Digitally signed by Alexander P.

Runko -S

Runko -S

Date: 2021.06.22 16:34:42 -04'00'

Alexander Runko, Ph.D.

Director

Division of Investigative Oversight

Office of Research Integrity

From: Sharphorn, Dan

To: saprakas@utmb.edu; loprakas@utmb.edu; juyoon@utmb.edu

Cc: <u>Peter Weinstein; King, Carrie - UTMB</u>

Subject: Complaint

Date: Friday, November 12, 2021 4:26:12 PM

Attachments: <u>image001.png</u>

Dear Drs. Prakash, Prakash, and Yoon,

Your "formal complaint" dated November 1, 2021, has been referred to me.

As you know, the inquiry and investigation about which you complain has been withdrawn and the subject allegations are being reviewed de novo in accord with applicable policies and procedures.

Your complaints are duly noted, but the de novo review is your sole remedy at this time.

Cc: Peter Weinstein Carrie King

Daniel H. Sharphorn
Vice Chancellor and General Counsel
The University of Texas System
210 West 7th Street
Austin, Texas 78701
512-499-4462

dsharphorn@utsystem.edu



November 16, 2021

Daniel H. Sharphorn Vice Chancellor and General Counsel University of Texas 210 West 7th Street Austin, TX 78701 Tel: (512) 499-4462

Fax: (512) 499-4523 dsharphorn@utsystem.edu

Dear Mr. Sharphorn,

We were stunned by your email sent to us on Friday November 12, 2021. After over two years of abuse by Dr. Nisha Garg through improper and illegal investigations into an honest mistake, you now inform us that the architect of the travesty we have suffered through will not be held to account. Nor will those, like President Raimer and Carolee King and others who allowed Dr. Garg through their failed oversight to abuse us for two years. This is beyond disappointing. It is incontrovertible that Dr. Garg through her improper and illegal "investigations" violated UTMB's PPMIR, the University of Texas' Regents Rules of Conduct and broke federal law under 42 C.F.R. Part 93. This is well documented and clearly is what led to Dr. Garg being terminated (at a minimum constructively) from her role as Scientific Integrity Officer.

So now we bring a complaint against Dr. Garg for her illegal and improper acts and your response is that the last two plus years did not occur and we are to just start over with a new inquiry into the same honest mistake. So, while we have to continue to suffer more, Dr. Garg and others who clearly broke the rules and law get a pass. This is not just unfair, but a travesty.

We once again ask that you and your office open an investigation into Dr. Garg's actions and those who failed to provide proper oversight under the Regents Rules of Conduct as requested in our letter of November 1, 2021. Failure to start such an investigation immediately will force us to look for redress through other avenues for the significant and purposeful damage and harm we have all suffered and particularly, Dr. Yoon.

Finally, you ask us to just go along with a new inquiry run by UTMB with your input. Based on the last two years plus, including your response on Friday November 12 to our complaint, how could we have any faith in the objectivity of an inquiry by UTMB into what was clearly an honest mistake? Obviously, we

cannot, since at no time have our interests and the harm we have suffered been considered or an attempt made to rectify them.

In the end, we are dumbfounded at where this process has taken us and we are beyond disappointed. Still, we hope that you will take our complaint seriously and that the responsible individuals will be held accountable.

Best regards,

Louise Prakash, PhD

Professor

Biochemistry and Molecular Biology

Satya Prakash, PhD

Satya Pracosh

Professor

Biochemistry and Molecular Biology

Jung-Hoon Yoon, PhD

Research Scientist III

Any proof on

Biochemistry and Molecular Biology



David Niesel, PhD. Scientific Integrity Officer

5.106 Administration Building 301 University Boulevard Galveston, TX 77555-0539 O 409.772.2667 F 409.772.9598

March 2, 2022

Jung-Hoon Yoon, Ph.D.
Department of Biochemistry and Molecular Biology
University of Texas Medical Branch
301 University Blvd.
Galveston, TX 77555-1061

Dear Dr. Yoon:

On October 5, 2021, I was asked by UTMB President, Dr. Ben Raimer to assume the role of Scientific Integrity Officer ("SIO") at UTMB. I have a long history in research at UTMB. I have been a faculty member at UTMB in the Department of Microbiology and Immunology since 1983 and became the Department Chairman in 2000. Additionally, I have been the Senior Vice President and Dean of the Graduate School of Biomedical Sciences and was later appointed as Chief Research Officer. I retired from UTMB in January 2021. Since then, I have been a part-time adjunct professor.

I understand that you are a Respondent in an allegation of research misconduct, the specifics of which I have included in Exhibit A. I have heard from the Office of Research Integrity ("ORI") that due to the fact that the research misconduct allegations relate to research funded by the Public Health Service, UTMB is obligated to complete its review of this case in order to fulfil its responsibilities under 42 CFR Parts 50 and 93. In consultation with ORI, UTMB has determined that the best course of action is to restart the case from receipt of the allegation with a new SIO and committee members. As I take over this process, I want to reassure you that the previous January 2, 2020 Scientific Integrity Committee report will not be utilized and will be disregarded. I also assure you that I will follow all UTMB protocols and procedures established for these matters.

In this regard, I have initiated this case beginning with an assessment phase in which I reviewed the original allegation and determined that there is sufficient cause to initiate an inquiry into this matter. I ask for your cooperation as the Respondent. Specifically, UTMB's Policy and Procedure Manual on Integrity in Research states, "Institutional members will cooperate with the [Scientific Integrity Officer] and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the SIO or other institutional officials." Furthermore, such failure or refusal will require reporting to ORI and the National Institutes of Health, the funding agency of the grants, for additional action.

UTMB has established an *ad hoc* scientific integrity committee for this purpose that does not include members of the current Scientific Integrity Committee who were involved in your case previously. A listing of committee members approved by Dr. Raimer is:

Mahmoud Ahmed, PhD William Calhoun, MD Michael Kinsky, MD, PhD Shinji Makino, PhD Anthony Okorodudu, MD Huey-Ming Tzeng, PhD Gracie Vargas, PhD

The inquiry committee may be a subset of this group, and you will be informed of such subset following the appointment of such inquiry committee.

As per our policies, we provide this roster for your review. Please let me know in writing within 5 business days of the date of this letter if there are any personal, professional, or financial conflicts of interest with these scientists participating in this process.

I have identified sequestered materials you provided to Dr. Garg, the former SIO. I may be reaching out to you for help in obtaining additional materials and will be in touch with specific requests.

Please know that I come to this role unbiased and focused on helping you and the committee navigate this process. My role is to manage the process, to keep it fair and to respect your rights. I have no role in the decision process at the committee or institutional level. Also, I am aware of the time involved and am focused on completing this process in a timely and fair manner. I welcome your comments at any time. I realize that you have retained legal counsel and will take steps to ensure all are kept informed as we proceed in this important process. In the next weeks, I will schedule an interview with you so I understand your views and response(s) to this allegation. Please refer to UTMB's Policy and Procedure Manual on Integrity in Research for information regarding the inquiry process and your rights and responsibilities during the process. I know this is a stressful time for you, but I will work to expedite this process. This is an important process for you as well as UTMB.

Sincerely,

David W. Niesel, PhD

Scientific Integrity Officer

CC:

Peter Weinstein
Entralta P.C., a Litigation, Intellectual Property and Business Law Firm 4500 Williams Drive, Suite 212, PMB 511
Georgetown, TX 78633

P: 805-444-7865, E: peter.weinstein@entralta.com

Attachments - UTMB's Policy and Procedure Manual on Integrity in Research

Exhibit A - Specific Allegations of Research Misconduct

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N6-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019). The complainant who wishes to remain anonymous alleged that there were discrepancies in Supplemental Figure S2:

Panel A - top left: blot for TLS Pol in NC/Polrr samples is from another blot for a different protein.

Panel A - middle left: Polcp data is from another blot for a different protein in different cells, Revl blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Poh data are from a blot for another protein.

Panel B- Western blot for Poh and tubulin for NC/Pol<p samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Revl samples are falsified from other data

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Entralta P.C. 1560-1 Newbury Road, Suite 327 Thousand Oaks, California 91320

Peter D. Weinstein, Ph.D., J.D.
Phone: 805-444-7865
Fax: 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

March 3, 2022

David Niesel, Ph.D. Scientific Integrity Officer 5.106 Administration Building 301 University Boulevard Galveston, TX 77555-0539 Tel: (409) 772-2667

Fax: (409) 772-9598 @utsystem.edu

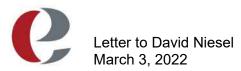
Dear Dr. Niesel,

As you would expect, my clients and I are disappointed that you have decided to launch an inquiry. It is not clear to us that there are any grounds to initiate the inquiry based on the evidence known to all parties. Saying that, one issue that I believe we should address at the outset is the standard by which Dr. Yoon will be judged. It is not clear that your predecessor ever truly understood that research misconduct and the requirements for a finding of research misconduct are defined under United States law as set forth in Title 42, Chapter I, Subchapter H, Sections 93.103 and 93.104.

More particularly, Section 93.103 identifies what constitutes research misconduct. What is interesting is that research misconduct under Sections 93.103(a) - (c) means that the research misconduct constitutes "fabrication, falsification or plagiarism" of the research results. Section 93.103(d) states that research misconduct "does not include honest error or difference of opinion."

Section 93.104 sets forth the standard for finding research misconduct. This includes Section 93.104(a) that requires that the conduct "be a significant departure from accepted practices of the relevant research community" and pursuant to Section 93.104(b) that that the "misconduct be committed, knowingly, intentionally or recklessly." It is based on these sections and their subsections that Dr. Yoon is to be judged.

As Dr. Yoon's inquiry is essentially based on whether he violated Section 93.103 and Section 93.104, I believe that it would be valuable for you and me to meet to discuss the guidelines by which the inquiry will be conducted. I believe that it would help if both sides had a clear understanding of how the laws Dr. Yoon will be adjudged are being interpreted and the standards the SIC will be asked to follow in making their judgment. In some ways, I view this in the same manner as the handling of jury instructions by plaintiff's and defendant's counsel. As you may



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know, it is common for plaintiff's and defendant's counsel to work together to provide the instructions regarding the legal standards by which a jury will judge the case before them.

I know at some level this may considered a big ask but based on the history of the three prior inquiries conducted by your predecessor into Dr. Yoon on this matter, I believe that it is a wholly reasonable request. Finally, as I believe that he is advising you on the legal aspects of this inquiry, it would likely be helpful to have Daniel Sharphorn attend this meeting.

I am available on March 7 and 8 as well as March 14 and 15 to meet. I can come to Galveston to meet or we can meet in Austin if Mr. Sharphorn will attend. I look forward to your prompt reply.

Best regards,

Peter D. Weinstein

From: Sharphorn, Dan
To: Peter Weinstein

Cc: Hebbar, Rohan - UTMB; King, Carrie - UTMB

Subject: FW: Communication re Yoon inquiry

Date: Wednesday, March 16, 2022 3:38:26 PM

Attachments: <u>image001.png</u>

image001.jpg ATT00001.htm

Letter to Dr. David Niesel.pdf

ATT00002.htm

Dr. Weinstein,

Your March 3 letter to Dr. David Niesel eventually made its way to my desk.

With that we have received your opinion on what process Dr. Niesel should follow in the inquiry into Dr. Yoon's conduct, but see no reason to have a preliminary meeting for you to further explain your view. Dr. Niesel will continue to address all communications directly to Dr. Yoon with you Cc'd per UTMB's normal process with research misconduct respondents.

I must add that I am surprised that you sent your letter directly to Dr. Niesel. I note that you copied Rohan Hebbar on the email transmission, but not on the letter itself. Confusion is added by the fact that your letter to Dr. Niesel is marked as "CONFIDENTIAL: ATTORNEY-CLIENT PRIVILEGE." A direct communication to Dr. Niesel, marked "attorney-client privilege," is clearly improper.

Please send any future communications for Dr. Niesel directly to me, Carrie King, or Mr. Hebbar. Dr. Niesel will be in touch with your client soon to schedule an interview. You will be included on such communication and invited to attend subject to UTMB's Procedure Manual on Integrity in Research which states in relevant part that "[I]awyers or other personal advisors may be present at interviews and proceedings, but their participation will be strictly limited to advising the Respondent."

Dan Sharphorn

Daniel H. Sharphorn
Vice Chancellor and General Counsel
The University of Texas System
210 West 7th Street
Austin, Texas 78701
512-499-4462
dsharphorn@utsystem.edu
cid:image003.png@01D7D617.1956F4C0

?

From: King, Carolee A. (Legal) <caaking@UTMB.EDU>

Sent: Friday, March 4, 2022 10:38 AM

To: Sharphorn, Dan <dsharphorn@utsystem.edu> **Subject:** Fwd: Communication re Yoon inquiry

EXTERNAL MAIL

This email originated outside of The University of Texas System Administration. Please exercise caution when clicking on links or opening attachments.

FYI-

Sent from my iPhone

Begin forwarded message:

From: "Hebbar, Rohan" < rohebbar@UTMB.EDU>

Date: March 4, 2022 at 8:30:08 AM CST

To: "King, Carolee A. (Legal)" < caaking@UTMB.EDU>

Subject: FW: Communication re Yoon inquiry

FYI more from Yoon's attorney attached.

From: Peter Weinstein < <u>Peter.Weinstein@entralta.com</u>>

Sent: Thursday, March 3, 2022 8:38 PM **To:** Niesel, David W. <<u>dniesel@UTMB.EDU</u>>

Cc: Comvalius-Goddard, Sharon A. < <u>sacomval@UTMB.EDU</u>>; Hebbar, Rohan < <u>rohebbar@UTMB.EDU</u>>; Peter Weinstein < <u>Peter.Weinstein@entralta.com</u>>

Subject: Communication re Yoon inquiry

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Niesel,

Please see my letter attached hereto.

Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D.

Managing Partner



David Niesel, PhD. Scientific Integrity Officer

5.106 Administration Building 301 University Boulevard Galveston, TX 77555-0539 O 409.772.2667 F 409.772.9598

April 18, 2022

Jung-Hoon Yoon, Ph.D.

Department of Biochemistry and Molecular Biology
301 University Blvd
Galveston, TX 77555-1061

Dear Dr. Yoon:

I am writing to schedule an interview with you to discuss allegations of scientific misconduct reported to the Scientific Integrity Office. The details of the allegations were provided to you in a previous communication dated March 2, 2022. This interview is consistent with UTMB's policy and process to maintain the highest level of scientific integrity on our campus. This will be a time to understand your response to these allegations and will be used to inform the *ad hoc* scientific integrity committee ("*ad hoc* Committee").

This interview will be conducted virtually using Teams and will be recorded. You have the right to retain legal counsel at your own expense and we understand that you have retained Peter D. Weinstein, Ph.D., J.D. as your attorney on this matter. We have copied Dr. Weinstein on this letter and will continue to copy him unless/until you instruct us otherwise. Your legal counsel or a non-legal advisor may be present during the interview and any subsequent interview or meeting that takes place during the process, but their participation will be strictly limited to advising you.

The interview will focus on information we received regarding data presented in Supplemental Fig. S2 of your Genes and Development article volume 33:282-287, 2019 which alleges discrepancies in the Western blot data presented. This is outlined below. If this information is incorrect, I would like to see the correct information in a laboratory notebook. I am aware of the correction you have submitted to the journal which I will present to the committee.

Allegations:

1) In Panel A:

- a. In the lanes labeled NC and Pol η , the bands appear to come from a notebook that are labeled Ela and NC
- b. In the second row, images presented are highly similar to ~40kDa bands in a notebook page (different protein) that are labeled to be non-specific background used for Polθ. Also, REV 1 blot appears to be the mirror image.
- c. The Rev7 images appear to be highly similar to ~150kDa bands for a different protein that are labeled differently. Tubulin data appear to be from a different experiment.
- d. β-tubulin appear to be from a different cell line and experiment from 10-13-14
- e. Lane labeled siRNA, Rev -7 highly similar to ~150kDa bands from WB 5 (WAPAL).

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f. Polζ - Top row appears to be mirror image from WB 7 – Poli data appear to be from a blot for another protein.

2. In Panel B:

a. Results appear identical to a different experiment in different lab notebooks

3. In Panel C:

a. NC & Rev image bands are highly similar to those in a notebook from another experiment.

I will want to know how/why the questioned original manuscript figures were utilized. Additional questions will address how this data was assembled and others that were involved in this process. After the interview, I will prepare a report for the *ad hoc* Committee regarding our discussion and my review of all relevant data or materials. I may also prepare a charge for the *ad hoc* Committee to commence the inquiry process. The purpose of the inquiry is to conduct an initial review of the evidence to determine if an investigation is warranted, not to determine whether research misconduct definitely occurred. The *ad hoc* Committee may wish to speak to you and/or other witnesses involved in the research. I forwarded you a list of all the faculty members who will constitute the ad hoc Committee in a previous communication dated March 2, 2022.

Our interview is scheduled for April 26, 2022 at 10 am and I will send out a Teams meeting link for this date and time. If that date or time does not work for you, please let me know via email (dniesel@utmb.edu) within five (5) days of the date of this letter. Furthermore, please let me know within five (5) days of the date of this letter whether you plan on having an attorney advisor present at the interview so that I can inform UTMB's Department of Legal Affairs since they will require presence at the meeting as well.

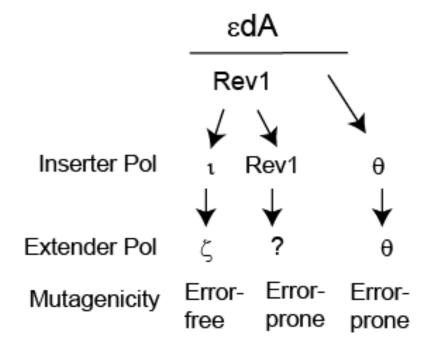
I am committed to proceeding ahead and will ensure that this will be a fair process. Please contact me with questions at any time.

Sincerely,

David W. Niesel, PhD

Professor and Scientific Integrity Officer

TLS pathways for replicating through etheno-dA in human cells



Supplemental Table S1

Effects of siRNA knockdown of TLS polymerases on the replicative bypass of the εdA lesion carried on the leading strand template in wild type, Rev1^{-/-}, or Polθ^{-/-} MEFs

MEFs	siRNA	Number of Kan* colonies	Number of blue colonies among Kan ⁺	TLS (%)	
WT	NC	422	94	22.3	
	NC	350	28	8.0	
Davids/	Poli	308	26	8.4	
Rev1-/-	Rev3	296	24	8.1	
	Polθ	411	4	1.0	
Pol0 ^{-/-}	NC	387	44	11.4	
	Poli	432	15	3.5	
	Rev3	408	14	3.4	
	Rev1	367	4	1.1	

Supplemental Table S3

Effects of catalytically active (WT) Rev1 or catalytically inactive D570A E571A mutant Rev1 on TLS opposite εdA carried on the leading strand template in Rev1- MEFs

Vector expressing	Number of Kan ⁺ colonies	Number of blue colonies among <i>Kan</i> ⁺	TLS (%)	TLS pathway that remains active	
_	458	38	8.3	Polθ	
WT Rev1	364	70	19.2	Polι/Polζ, Rev1 Pol, Polθ	
Catalytic mutant Rev1	306	48	15.7	Polι/Polζ, Polθ	

Supplemental Table S5

Effects of catalytically active (WT) or catalytically inactive D2540A E2541A mutant (1708-2590) Pol θ on TLS opposite ϵ dA carried on the leading strand template in Pol θ - ℓ -MEFs

Vector expressing	Number of Kan ⁺ colonies	Number of blue colonies among <i>Kan</i> ⁺	TLS (%)	TLS pathways that remain active
_	381	42	11.0	Pol ₁ /Polζ, Rev1 Pol
WT Polθ	332	73	22.0	Pol ₁ /Polζ, Rev1 Pol, Polθ
Catalytic mutant Polθ	295	31	10.5	PolιPolζ, Rev1 Pol

Supplemental Table S6

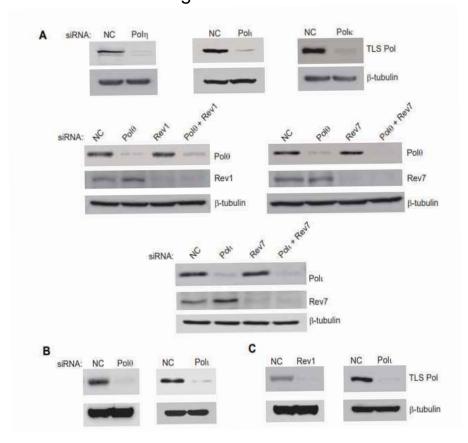
Effect of wild type Pol θ , catalytically active (WT) Rev1, or catalytically inactive D570A E571A mutant Rev1 on mutation frequencies and nucleotides inserted opposite ϵ dA carried on the leading strand DNA template in wild type, Rev1 $^{+}$, or Pol θ $^{+}$ MEFs

MEFs	Vector expressing, siRNAs	No. of Kan+ blue colonies sequenced	Nucleotide inserted				Mutation frequency (%)	Error-prone TLS pathway that remains
			Α	G	С	Т	(**)	active
WT	None	96 (12) ^a	3	0	9	84	12.5	Rev1,Polθ
Pol0 ^{-/-}	Vector control	96 (9)	1	0	8	87	9.4	Rev1
Rev1 ^{-/-}	Vector control	96 (8)	4	0	4	88	8.3	Polθ
Rev1 [⊬] (mPolθ siRNA) ^b	Flag-Mutant - Rev1	90 (0)	0	0	0	90	0	none

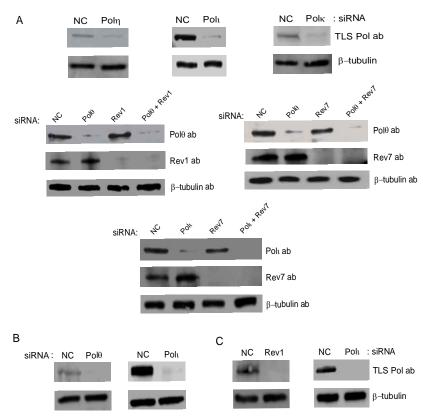
^aNumber of colonies where TLS occurred by insertion of a nucleotide other than T are shown in parentheses.

^bRev1^{-/-}MEFs were treated with mPolθ siRNA. In these MEFs carrying Flag-mutant Rev1, only the Pol₁/Polζ dependent error-free pathway remains active.

Figure S2



Corrected Figure S2





See original article: Yoon et al. 33 (5-6): 282.

Corrigendum: DNA polymerase θ accomplishes translesion synthesis opposite 1,N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash and Satya Prakash

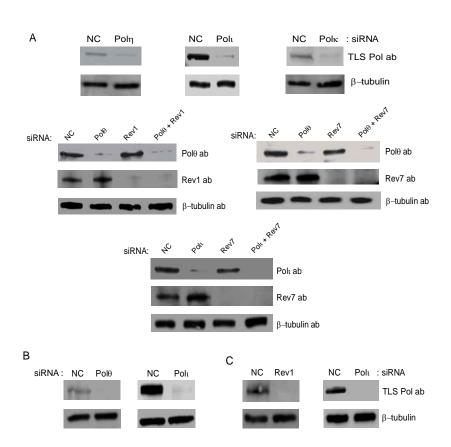
Genes & Development 33: 282-287 (2019)

In Supplemental Figure S2 in the above article, we have been unable to confirm that the Western blots in panels A-C were assembled correctly. Because of our concerns about the accuracy of the data in the Western blots, we are presenting a new set of verified experiments in the new Supplemental Figure S2, which can be found in the Revised Supplemental Material online. This change in no way affects any of the results or conclusions of this study. The authors apologize for this error.

doi: 10.1101/gad,334946.119

Published by Cold Spring Harbor Laboratory Press

Corrected Figure S2





Implications of inhibition of Rev1 interaction with Y family DNA polymerases for cisplatin chemotherapy

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satya Prakash

Department of Biochemistry and Molecular Biology, University of Texas Medical Branch, Galveston, Texas 77555, USA

Chemotherapy with cisplatin becomes limiting due to toxicity and secondary malignancies. In principle, therapeutics could be improved by targeting translesion synthesis (TLS) polymerases (Pols) that promote replication through intrastrand cross-links, the major cisplatin-induced DNA adduct. However, to specifically target malignancies with minimal adverse effects on normal cells, a good understanding of TLS mechanisms in normal versus cancer cells is paramount. We show that in normal cells, TLS through cisplatin intrastrand cross-links is promoted by Poln- or Pol-dependent pathways, both of which require Rev1 as a scaffolding component. In contrast, cancer cells require Rev1-Pol\(\zeta\). Our findings that a recently identified Rev1 inhibitor, JH-RE-06, purported to specifically disrupt Rev1 interaction with Pol\(\zeta\) to block TLS through cisplatin adducts in cancer cells, abrogates Rev1's ability to function with Y family Pols as well, implying that by inactivating Rev1-dependent TLS in normal cells, this inhibitor will exacerbate the toxicity and tumorigenicity of chemotherapeutics with cisplatin.

[Keywords: DNA repair; nucleotide excision repair; translesion synthesis; Y family DNA polymerases; cisplatin intrastrand cross-links; Rev1]

Supplemental material is available for this article.

Received May 11, 2021; revised version accepted July 15, 2021.

----Original Message-----

From: Oddo, Dorothy <doddo@cshl.edu> Sent: Saturday, July 17, 2021 7:09 PM To: Prakash, Satya <saprakas@UTMB.EDU>

Subject: Publicity efforts on the Yoon-Prakash manuscript

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Prakash,

Congratulations on having your paper, "Implications of inhibition of Rev1 interaction with Y-family DNA polymerases for cisplatin chemotherapy," by Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satya Prakash, accepted for publication in the September 2021 issue of Genes & Development.

We wanted to get in touch with you regarding potential publicity efforts for your G&D manuscript. We are optimistic that general media outlets &/or other scientific journals – such as Science, Nature, Nature Reviews - might be interested in covering this. To facilitate this, we would like to get in touch with the media affairs contact at your institution to see if/what publicity efforts they have planned for your upcoming paper.

If you could please send me the appropriate contact name and e-mail address for someone at your institution I will look into this.

Thanks very much for all of your help,

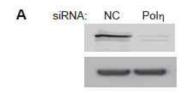
Dorothy Oddo

Editorial Office

Genes & Development

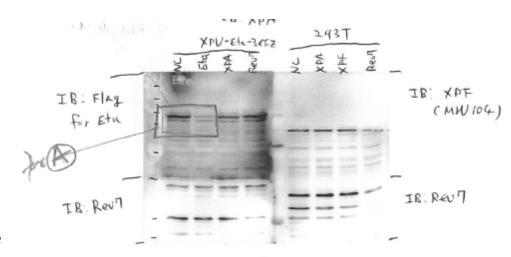
Response for Panel A. a.

From originally published Fig. S2



What was used for panel A.a. is Pol eta but there is more space in the 2 bands in evidence file

From what was sent in evidence file



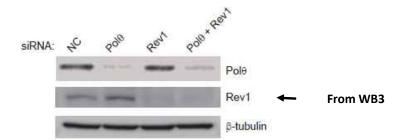
Response for Panel A. b.

WB3

10-3-13

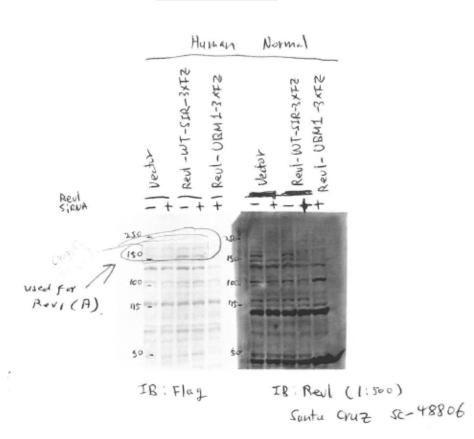
WB3

From originally published Fig. S2



It's hard to tell because bands in evidence file do not show up well and they would have to be the mirror image of what was published; and the Rev1 band in lane 2 is curved more than in the evidence file

From what was sent in evidence file

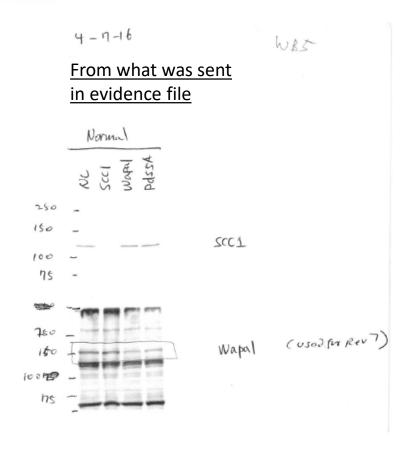


Response for Panel A.c/A.e.

- c. The Rev7 images appear to be highly similar to ~150kDa bands for a different protein that are labeled differently. Tubulin data appear to be from a different experiment.
- d. β-tubulin appear to be from a different cell line and experiment from 10-13-14
- e. Lane labeled siRNA, Rev -7 highly similar to ~150kDa bands from WB 5 (WAPAL).

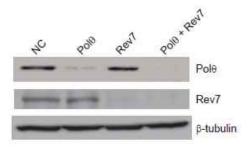
From originally published Fig. S2 Pole Rev7 Prom WB5

The intensity of the 2 bands on the right in the evidence file show up fairly well but they don't in Fig. S2.



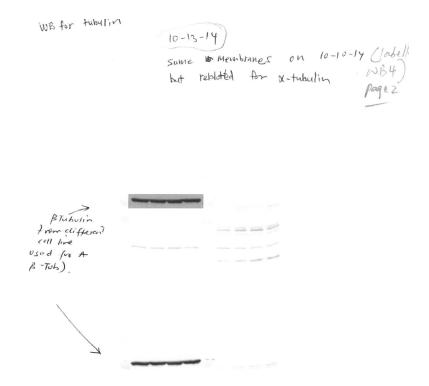
Response for Panel A. d.

From originally published Fig. S2



Tubulin bands are supposed to have come from 10-13-14. Since the evidence file is supposed be stripped and reblotted blot of 10-10-14 (WB4), it's very hard to tell which blot was actually stripped and reprobed.

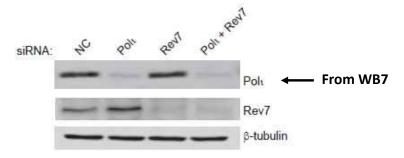
From what was sent in evidence file



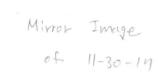
Response for Panel A.f.

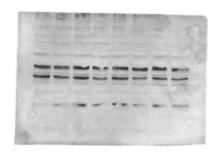
From what was sent in evidence file

From originally published Fig. S2



In Fig. S2, lane 3 seems to curve upward to a greater extent than in blocked portion of the evidence file. There is no labelling on the evidence file.









Mirror image

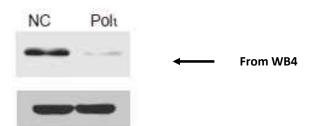
WBn

Response for Panel B.a.

WB4

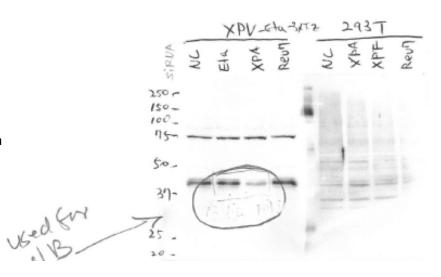
From what was sent in evidence file

From originally published Fig. S2



10-10-14

In Fig. S2, there is no doublet in band in NC lane but there is one in the evidence file. Also, left part of Pol ι band in lane 2 of Fig S2 is less intense than right portion whereas intensity of band in Evidence file is more uniform



Response for Panel C.a.

WB 1

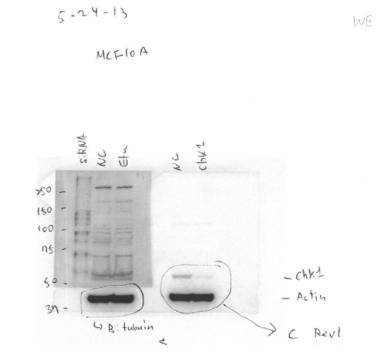
From originally published Fig. S2

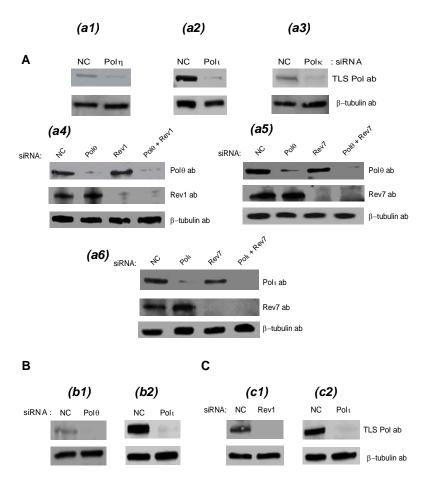
C NC Rev1 From WB1

In Fig. S2, lane 1, NC, shows more curvature than in evidence file. Also, in lane 2 of Fig. S2, Rev1 band is not visible and left side Rev1 band is more darker than right side but in evidence file, right side is more darker.

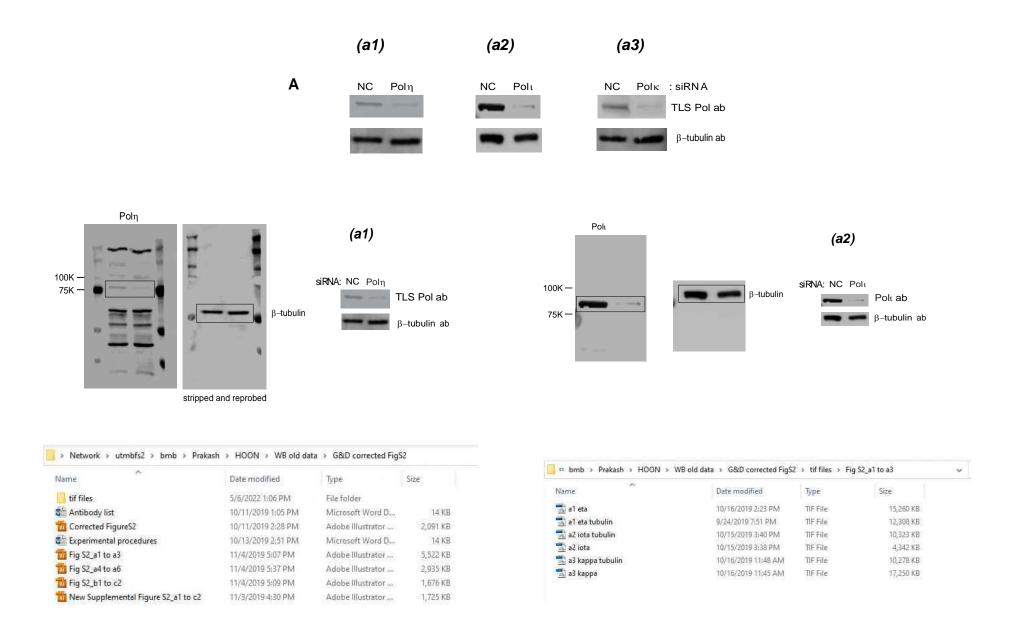
Tubulin bands do not match.

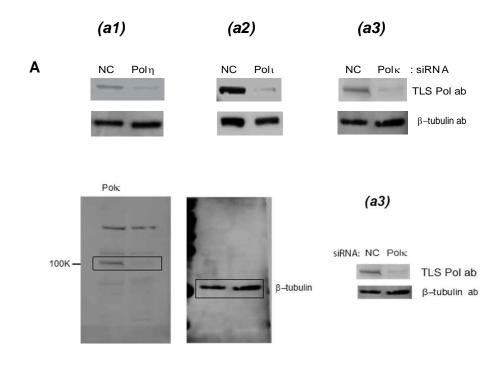
From what was sent in evidence file

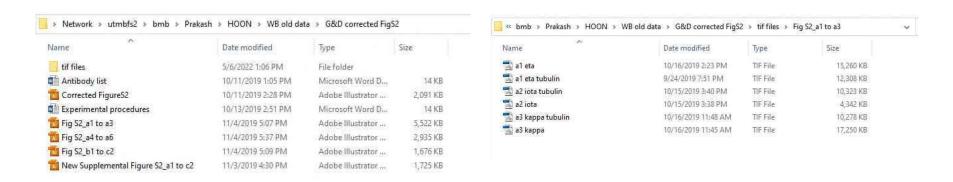


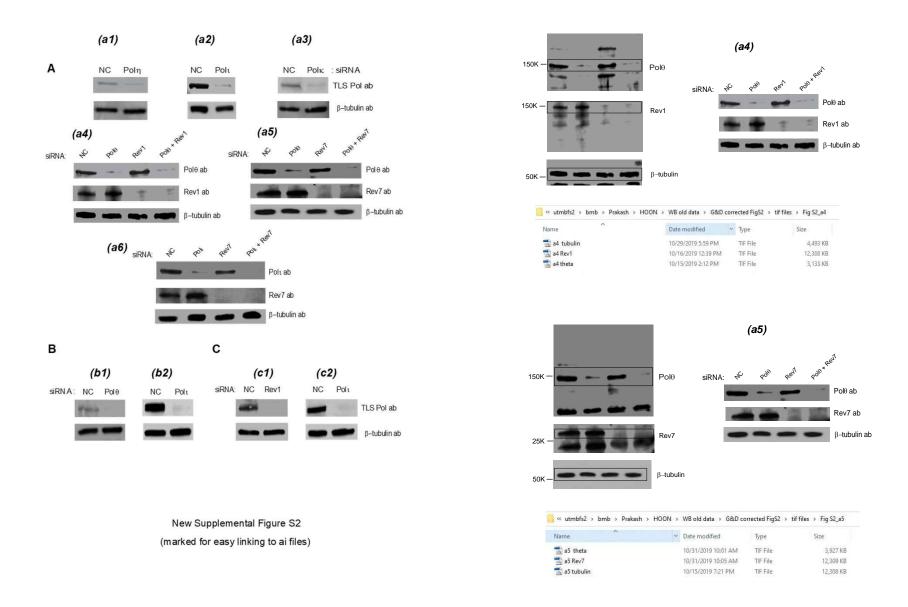


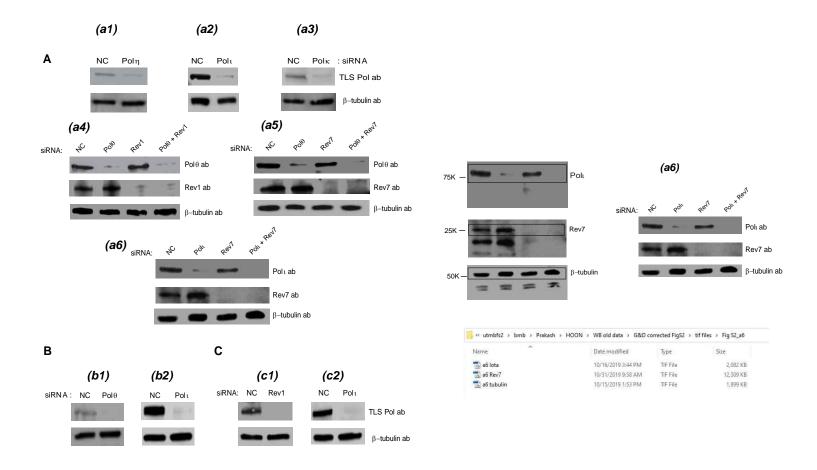
New Supplemental Figure S2 (marked for easy linking to ai files)



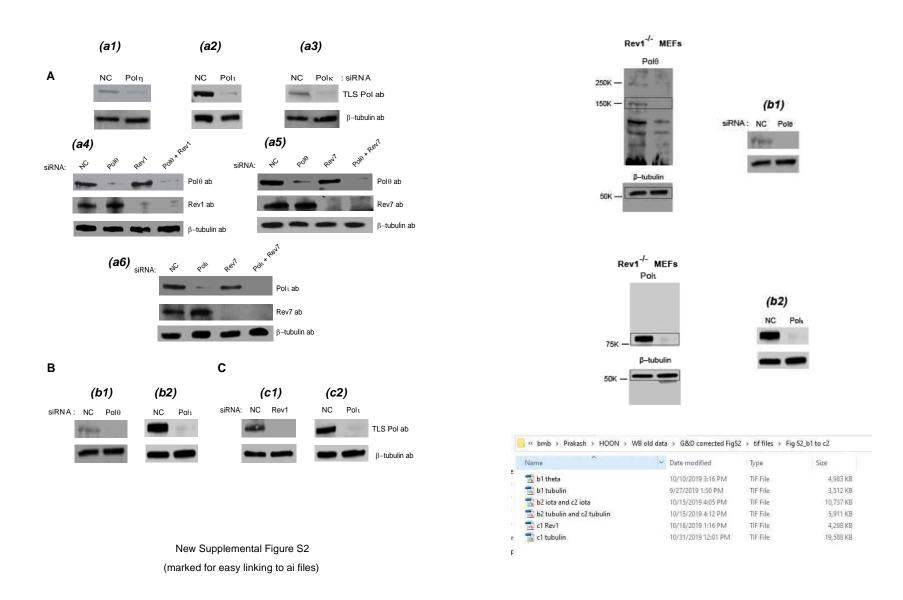


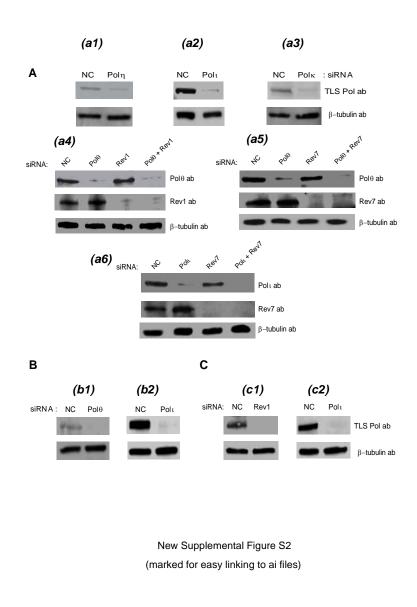


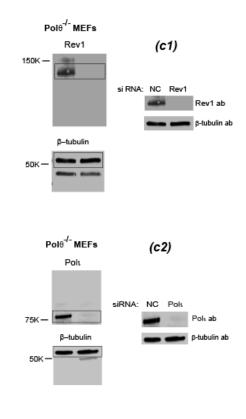


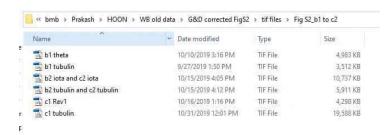


New Supplemental Figure S2 (marked for easy linking to ai files)









From: Peter Weinstein

To: <u>Niesel, David W.</u>; <u>Peter Weinstein</u>; <u>Hebbar, Rohan</u>

Subject: RE: Interview Transcript

Date: Wednesday, June 8, 2022 8:07:55 PM

Dear Dr. Niesel,

It has been almost three weeks since Dr. Yoon's interview. I was just following up to see if there is anything else you need from us to help you prepare your report. As always, please feel free to contact me with any additional requests or questions.

Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D. Managing Partner



Entralta P.L.L.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive
Suite 212, PMB 511
Georgetown, TX 78633
P 805-444-7865
F 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

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From: Niesel, David W. <dniesel@UTMB.EDU>

Sent: Thursday, May 19, 2022 11:03 AM

To: Peter Weinstein < Peter. Weinstein@entralta.com>; Yoon, Jung hoon < juyoon@UTMB.EDU>;

Hebbar, Rohan < rohebbar@UTMB.EDU>

Subject: Interview Transcript

All:

Please find the attached meeting transcript. Please make corrections as the transcription is not perfect. Use redlines to indicate changes. Thank you for your comments.

Regards,

Dave

 From:
 Hebbar, Rohan

 To:
 Peter Weinstein

 Subject:
 RE: Interview Transcript

Date: Wednesday, June 8, 2022 9:00:32 PM

Attachments: image002.png

Peter,

Please direct your communications directly to me on this matter. We did receive the DropBox link and Dr. Niesel will contact your client with you Cc'd in the event he has additional requests or questions.

Thanks, Rohan

Rohan Hebbar, JD, LLM
Department of Legal Affairs
Assistant Vice President
The University of Texas Medical Branch at Galveston
301 University Blvd.
Galveston, TX 77555-0171
Phone: (409) 747-8743



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From: Peter Weinstein < Peter. Weinstein@entralta.com >

Sent: Wednesday, June 8, 2022 8:08 PM

To: Niesel, David W. <dniesel@UTMB.EDU>; Peter Weinstein <Peter.Weinstein@entralta.com>;

Hebbar, Rohan < rohebbar@UTMB.EDU>

Subject: RE: Interview Transcript

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It has been almost three weeks since Dr. Yoon's interview. I was just following up to see if there is anything else you need from us to help you prepare your report. As always, please feel free to contact me with any additional requests or questions.

Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D. Managing Partner



Entralta P.L.L.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive
Suite 212, PMB 511
Georgetown, TX 78633
P 805-444-7865
F 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

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From: Niesel, David W. <dniesel@UTMB.EDU>

Sent: Thursday, May 19, 2022 11:03 AM

To: Peter Weinstein < Peter.Weinstein@entralta.com>; Yoon, Jung hoon < juyoon@UTMB.EDU>;

Hebbar, Rohan < rohebbar@UTMB.EDU >

Subject: Interview Transcript

All:

Please find the attached meeting transcript. Please make corrections as the transcription is not perfect. Use redlines to indicate changes. Thank you for your comments.

Regards,

Dave

From: Niesel, David W. <dniesel@UTMB.EDU>
Sent: Wednesday, June 22, 2022 8:13 PM
To: Yoon, Jung hoon; Peter Weinstein

Cc: Comvalius-Goddard, Sharon A.; Hebbar, Rohan; Martinez, Esther J.

Subject: Follow up

Hello Dr. Yoon:

The *ad hoc* SI committee has met and discussed your case. Dr William Calhoun is chairing this committee. They would like to hear your presentation and have agreed to an in-person meeting. Esther Martinez in Dr. Sharon Comvalius-Goddard office will contact you to schedule a time. They indicated they would like to find a time \sim three weeks from now.

The committee has also requested the notebook where the information related to the experiments that repeated the Fig S2 Western blots be available to the committee. I am asking that this transfer occur tomorrow. Dr. Sharon Comvalius-Goddard will make arrangements for someone to come by your office to pick up this notebook. Please indicate where in the notebook this information is displayed and your office location. Copies of the notebook will be made and returned to your expeditiously.

Thank you for your help with this important process.

Regards,

Dave Niesel, PhD Scientific Integrity Officer UTMB From: Peter Weinstein

To: <u>Niesel, David W.</u>; <u>Yoon, Jung hoon</u>

Cc: <u>Hebbar, Rohan; Comvalius-Goddard, Sharon A.; Peter Weinstein</u>

Bcc: S Prakash

Subject: RE: Re-scheduling interview

Date: Wednesday, June 22, 2022 8:31:00 PM

Dear Dr. Niesel,

A couple of things. Dr. Hoon would prefer to do the meeting by video. Additionally, it is my understanding that the notebook you are requesting was actually maintained as an electronic file, all of which was given to you through the dropbox folder. If you would like, he can print out the documents, but in all honesty, it is a bit duplicative.

We were hoping to get this resolved by now. I believe there is a time limit to the inquiry under the UTMB PPMI and federal law, which I believe has been exceeded. I believe it definitely will be exceeded as we wait until the week of July 18 to do the next meeting.

Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D. Managing Partner



Entralta P.L.L.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive
Suite 212, PMB 511
Georgetown, TX 78633
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F 805-322-4469
peter.weinstein@entralta.com
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From: Niesel, David W. <dniesel@UTMB.EDU>

Sent: Monday, April 25, 2022 11:55 AM

To: Peter Weinstein < Peter. Weinstein@entralta.com>; Yoon, Jung hoon < juyoon@UTMB.EDU>

Cc: Hebbar, Rohan <rohebbar@UTMB.EDU>; Comvalius-Goddard, Sharon A.

<sacomval@UTMB.EDU>

Subject: Re: Re-scheduling interview

Drs. Yoon and Weinstein:

Thanks for the quick reply this morning. Let's set May 19th at 10am. I will be back in touch with logistic details. Mr. Hebbar will be joining from the UTMB side.

Regards,

Dave Niesel

From: Peter Weinstein < <u>Peter.Weinstein@entralta.com</u>>

Sent: Monday, April 25, 2022 8:26 AM

To: Niesel, David W. < dniesel@UTMB.EDU>; Yoon, Jung hoon < juyoon@UTMB.EDU>

Cc: Hebbar, Rohan <<u>rohebbar@UTMB.EDU</u>>; Comvalius-Goddard, Sharon A. <<u>sacomval@UTMB.EDU</u>>; Peter Weinstein <<u>Peter.Weinstein@entralta.com</u>>

Subject: RE: Re-scheduling interview

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Dear Dr. Niesel,

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Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D. Managing Partner



Entralta P.L.L.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive Suite 212, PMB 511 Georgetown, TX 78633 P 805-444-7865 F 805-322-4469 peter.weinstein@entralta.com www.entralta.com

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From: Niesel, David W. <<u>dniesel@UTMB.EDU</u>>

Sent: Monday, April 25, 2022 8:24 AM **To:** Yoon, Jung hoon < <u>iuyoon@UTMB.EDU</u>>

Cc: Peter Weinstein < reter-weinstein@entralta.com; Hebbar, Rohan reter-weinstein.com; Hebbar, Rohan reter-weinstein.com; Hebbar, Rohan reter-weinstein.com; Hebbar

Comvalius-Goddard, Sharon A. < sacomval@UTMB.EDU>

Subject: Re-scheduling interview

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Regards,

David Niesel, PhD Scientific Integrity Officer From: Peter Weinstein
To: Hebbar, Rohan

Cc: Comvalius-Goddard, Sharon A.; Niesel, David W.; Yoon, Jung hoon; Peter Weinstein

Subject: RE: Re-scheduling interview

Date: Thursday, June 23, 2022 12:18:00 PM

Attachments: <u>image001.png</u>

Dear Rohan,

Thanks for your email below. A couple of points. Due to the masking requirements at UTMB, we believe that having the meeting virtually will actually be preferable to everyone having to mask up in a room. I/we believe it will allow the committee to see Dr. Yoon and understand and appreciate his sincerity.

Second, on timing, as you are aware, this started in May 2019 and has been going on for about three years. We were told by Daniel Sharphorn in October that an inquiry would take place and now we are looking at the middle of July for the SIC meeting. You can understand the toll that this has taken on Dr. Yoon . I also believe you can understand that the continued draw out of an inquiry of what relates to an honest mistake is having on Dr. Yoon and how it is having a material effect on his mental and physical health.

If you need any more information or data, please let me know.

Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D. Managing Partner



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may not review, copy or distribute this message. If you have received this communication in error, please notify us immediately by e-mail and delete the original message.

From: Hebbar, Rohan <rohebbar@UTMB.EDU>

Sent: Thursday, June 23, 2022 12:05 PM

To: Peter Weinstein < Peter. Weinstein@entralta.com>

Cc: Comvalius-Goddard, Sharon A. <sacomval@UTMB.EDU>; Niesel, David W.

<dniesel@UTMB.EDU>; Yoon, Jung hoon <juyoon@UTMB.EDU>

Subject: RE: Re-scheduling interview

Dear Peter,

There will be an option for you and Dr. Hoon to attend virtually if that is your preference. An inperson inquiry committee meeting was scheduled to accommodate your request for same during Dr. Niesel's May 19th interview of Dr. Hoon. Please just let us know ahead of the meeting if you and your client change your mind and would like to attend in person so that we can plan accordingly.

We were initially unable to access the images you shared in the Dropbox folder, but have since reformatted them and are now able to access and share them with the committee. We will let you know if anything else is needed regarding these images.

Lastly, regarding time limits, since the inquiry committee is responsible for conducting the inquiry, the initiation of the inquiry occurs when the committee is given its charge and presented with the allegation. Since this occurred on June 20th, 2022, a meeting to interview Dr. Hoon in mid/late July would not result in a failure to comply with the time for completion set out in UTMB's PPMIR or federal law. Furthermore, as you know if Dr. Niesel, as the SIO determines that circumstances clearly warrant an extension, he may approve such extension utilizing the procedures outlined in the PPMIR.

Thanks, Rohan

Rohan Hebbar, JD, LLM
Department of Legal Affairs
Assistant Vice President
The University of Texas Medical Branch at Galveston
301 University Blvd.
Galveston, TX 77555-0171
Phone: (409) 747-8743



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From: Peter Weinstein < <u>Peter.Weinstein@entralta.com</u>>

Sent: Wednesday, June 22, 2022 8:32 PM

To: Niesel, David W. <<u>dniesel@UTMB.EDU</u>>; Yoon, Jung hoon <<u>juyoon@UTMB.EDU</u>>

Cc: Hebbar, Rohan <<u>rohebbar@UTMB.EDU</u>>; Comvalius-Goddard, Sharon A. <<u>sacomval@UTMB.EDU</u>>; Peter Weinstein <<u>Peter.Weinstein@entralta.com</u>>

Subject: RE: Re-scheduling interview

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Dear Dr. Niesel,

A couple of things. Dr. Hoon would prefer to do the meeting by video. Additionally, it is my understanding that the notebook you are requesting was actually maintained as an electronic file, all of which was given to you through the dropbox folder. If you would like, he can print out the documents, but in all honesty, it is a bit duplicative.

We were hoping to get this resolved by now. I believe there is a time limit to the inquiry under the UTMB PPMI and federal law, which I believe has been exceeded. I believe it definitely will be exceeded as we wait until the week of July 18 to do the next meeting.

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From: Niesel, David W. < dniesel@UTMB.EDU>

Sent: Monday, April 25, 2022 11:55 AM

To: Peter Weinstein < Peter.Weinstein@entralta.com; Yoon, Jung hoon < juyoon@UTMB.EDU>

Cc: Hebbar, Rohan < <u>rohebbar@UTMB.EDU</u>>; Comvalius-Goddard, Sharon A.

<sacomval@UTMB.EDU>

Subject: Re: Re-scheduling interview

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Regards,

Dave Niesel

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Cc: Hebbar, Rohan <<u>rohebbar@UTMB.EDU</u>>; Comvalius-Goddard, Sharon A. <<u>sacomval@UTMB.EDU</u>>; Peter Weinstein <<u>Peter.Weinstein@entralta.com</u>>

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To: <u>Peter Weinstein</u>

Cc: Comvalius-Goddard, Sharon A.; Niesel, David W.; Yoon, Jung hoon

Subject: RE: Re-scheduling interview

Date: Thursday, June 23, 2022 12:05:30 PM

Attachments: <u>image002.png</u>

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Sent: Wednesday, June 22, 2022 8:32 PM

To: Niesel, David W. <dniesel@UTMB.EDU>; Yoon, Jung hoon <juyoon@UTMB.EDU>

Cc: Hebbar, Rohan <rohebbar@UTMB.EDU>; Comvalius-Goddard, Sharon A. <sacomval@UTMB.EDU>; Peter Weinstein <Peter.Weinstein@entralta.com>

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Cc: Hebbar, Rohan <<u>rohebbar@UTMB.EDU</u>>; Comvalius-Goddard, Sharon A.

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Comvalius-Goddard, Sharon A. < sacomval@UTMB.EDU>

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Regards,

David Niesel, PhD Scientific Integrity Officer From: Niesel, David W.
To: Yoon, Jung hoon

Cc: Peter Weinstein; Hebbar, Rohan; Comvalius-Goddard, Sharon A.; Martinez, Esther J.

Subject: Additional Information

Date: Monday, June 27, 2022 10:47:04 AM

Good morning Dr. Yoon:

For the *ad hoc* SI committee, I am requesting information for the images you provided for the revised Fig. S2. While the titles for the figures does identify and sequence the images, additional notebook detail about the experiment would be helpful to the committee. A committee member did mention this as important information during their initial meeting.

Also, at the meeting of this committee, Dr. William Calhoun was designated to chair this committee.

We will provide the necessary link for you to present virtually to the committee.

Please let me know if you have questions.

Take care,

Dave Niesel

Details of experiments for revised Figure S2

Figure S2 a1

After samples were transferred to PVDF membrane, membrane was probed with Pol eta, then membrane was stripped and reprobed with β-tubulin antibody.

Figure S2 a2

After samples were transferred to PVDF membrane, membrane was cut around 65 Kda with razor blade. The part of the membrane above 65 Kda was probed with Pol iota antibody and the part of membrane below 65 Kda was probed with β-tubulin antibody.

Figure S2 a3

After samples were transferred to PVDF membrane, membrane was probed with Pol kappa antibody, then membrane was stripped and reprobed with β-tubulin antibody.

Figure S2 a4

After samples (lanes 1-4) were transferred to PVDF membrane, membrane was cut around 65 Kda with razor blade. The part of membrane above 65 Kda was probed with Pol theta antibody and the part of membrane below 65 Kda was probed with β -tubulin antibody. The other samples (lanes 6-8) in β -tubulin blot were for different experiments. Then, for Rev1 antibody, same amount (10 uL) of samples (lane1-4) were loaded on a new gel and transferred to membrane. Then membrane was probed with Rev1 antibody. Because I loaded same samples with same amount for Rev1 antibody. I didn't check β -tubulin for the loading control.

Figure S2 a5

After samples (lanes 1-4) were transferred to PVDF membrane, membrane was cut around 65 Kda with razor blade. The part of membrane above 65 Kda was probed with Pol theta antibody and the other part of membrane below 65 Kda was probed with β -tubulin antibody. Then, for Rev7 antibody, same amount (10 uL) of samples (lanes 5-8) were loaded on a new gel and transferred to membrane. Then membrane was probed with Rev7 antibody. Other samples (lane1-4) were for different experiments. Because I loaded same samples with same amount for Rev7 antibody. I didn't check β -tubulin for the loading control.

Figure S2 a6

After samples (lanes 1-4) were transferred to PVDF membrane, membrane was cut around 65 Kda with razor blade. The part of membrane above 65 Kda was probed with Pol lota antibody and the other part of membrane below 65Kda was probed with β-tubulin antibody. Then, for Rev7 antibody, same amount (10 uL) of samples (lanes 1-4) were loaded on a new gel and transferred to membrane and probed with Rev7 antibody. Other samples (lanes 5-6) were for different experiments.

Figure S2 b1 After samples were transferred to PVDF membrane, membrane was cut around 65 Kda with razor blade. The part of the membrane above 65 Kda was probed with Pol theta antibody and the other part of membrane below 65 Kda was probed with β-tubulin antibody.

Figures S2 b2 and C2

Samples in lanes 1-2 (NC, Pol iota depletion) were from Rev1 KO cells and samples in lanes 3-4 (NC, Pol iota depletion) were from Pol theta KO cells. After samples were transferred to PVDF membrane, membrane was cut around 65 Kda with razor blade. The part of the membrane above 65 Kda was probed with Pol lota antibody and the part of the membrane below 65 Kda was probed with β-tubulin antibody. Tubulin was in lanes 1-2 and 3-4.

Figure S2 c1

After samples (lanes 1-2) were transferred to PVDF membrane, membrane was cut around 65 Kda with razor blade. The part of the membrane above 65 Kda was probed with Rev1 antibody and the part of the membrane below 65 Kda was probed with β -tubulin antibody. Other samples (lanes 4-7) were for different experiments.

From: Peter Weinstein

To: Niesel, David W.; Yoon, Jung hoon

Cc: Comvalius-Goddard, Sharon A.; Hebbar, Rohan; Martinez, Esther J.; Peter Weinstein

Subject: RE: Follow up

Date: Wednesday, June 29, 2022 9:33:00 PM

Attachments: Details of experiments for revised Fig. S2 (003).pdf

Dear Dr. Niesel,

With regard to the follow up with Dr. Yoon, he is available at 10 AM or 11 AM on July 8. If that date does not work, then we will have to wait until the week of August 8 – either August 8, 9, 10 or 12, starting at 10 AM any day that week.

Additionally, please find the explanation of the figures you requested.

Sincerely,

Peter

From: Niesel, David W. <dniesel@UTMB.EDU> Sent: Wednesday, June 22, 2022 8:13 PM

To: Yoon, Jung hoon <juyoon@UTMB.EDU>; Peter Weinstein <Peter.Weinstein@entralta.com>

Cc: Comvalius-Goddard, Sharon A. <sacomval@UTMB.EDU>; Hebbar, Rohan <rohebbar@UTMB.EDU>; Martinez, Esther J. <ejmartin@UTMB.EDU>

Subject: Follow up

Hello Dr. Yoon:

The *ad hoc* SI committee has met and discussed your case. Dr William Calhoun is chairing this committee. They would like to hear your presentation and have agreed to an in-person meeting. Esther Martinez in Dr. Sharon Comvalius-Goddard office will contact you to schedule a time. They indicated they would like to find a time ~ three weeks from now.

The committee has also requested the notebook where the information related to the experiments that repeated the Fig S2 Western blots be available to the committee. I am asking that this transfer occur tomorrow. Dr. Sharon Comvalius-Goddard will make arrangements for someone to come by your office to pick up this notebook. Please indicate where in the notebook this information is displayed and your office location. Copies of the notebook will be made and returned to your expeditiously.

Thank you for your help with this important process.

Regards,

Dave Niesel, PhD Scientific Integrity Officer UTMB

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 405 of 514



Entralta P.L.L.C. 4500 Williams Dr., Ste 212 PMB 511 Georgetown, TX 78633

Peter D. Weinstein, Ph.D., J.D.
Phone: 805-444-7865
Fax: 805-322-4469
peter.weinstein@entralta.com
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July 14, 2022

Rohan Hebbar
Department of Legal Affairs
Assistant Vice President
The University of Texas Medical Branch at Galveston
301 University Boulevard
Galveston, TX 77555-0539
Tel: (409) 747-8743
rohebbar@utsystem.edu

Dear Rohan,

I wanted to follow up with you as we have not heard anything regarding scheduling an interview of Dr. Yoon with the Scientific Integrity Committee ("SIC"), since I sent an email to Dr Niesel on June 29, 2022. As you are aware, the Scientific Integrity Policy and Procedure Manual, Article V, "Conducting the Assessment and Inquiry," Clause G, "Time for Completion," states:

"The inquiry, including preparation of the final inquiry report and the decision of the President on whether an investigation is warranted, *must be completed within 60 calendar days of initiation of the inquiry*, unless the SIO determines that circumstances clearly warrant a longer period. If the SIO approves an extension, the inquiry record must include written documentation of the reasons for the extension." (*emphasis added*).

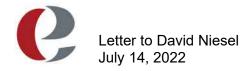
Dr. Niesel and you were aware of this 60 calendar day requirement. Indeed, Dr. Niesel brought it up at the end of his interview of Dr. Yoon. This is from the transcript that Dr. Niesel provided to you, Dr. Yoon and me on May 19, 2022:

00:42:35.770 --> 00:43:05.600

Niesel, David W.

And we have this initial meeting. If it moves forward, there is a fairly defined timeline that we need to meet. So I'm gonna ask them and I'll probably ask you to, you know, to be sensitive to that, that there are milestones. We need the meat and there's a time frame for for that. We can extend it. I'd rather not in the, you know, in the idea that we're going to try to move things forward expeditiously. OK, so.

It is clear that as of the date of the interview, Dr. Niesel was aware that there was a "defined timeline."



Now, Dr. Niesel informed Dr. Yoon that he was initiating the inquiry on March 2, 2026. Dr. Niesel then requested an interview with Dr. Yoon on April 26, 2022. For reference, the time from notice of the inquiry to the requested interview was 55 days. As you are aware, I was not available on April 26, so the interview took place on May 19, 2022. At the end of the interview, Dr. Niesel stated that he would try to expedite an SIC interview with Dr. Yoon as stated below:

00:38:24.800 --> 00:38:47.930

Niesel, David W.

Well, I'm going to. I have to prepare report and it'll take me a few days to do that. I will send out a invitation to committee members if not tomorrow, by early next week trying to get them together. And as you can imagine, getting faculty members together is another big challenge, right?

00:38:49.590 --> 00:38:55.650

Niesel, David W.

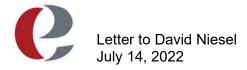
Because if everybody's busy schedule and but I expect this to move along rapidly.

Despite the alleged expediency, it was not until June 22, 2022 that Dr. Niesel informed Dr. Yoon and me that he wanted to schedule an interview with the SIC. The time between the interview and this follow-on request was another 34 days, for a total of 89 days at this point (I am not counting the time between April 26 to May 19 in my calculation). Then, on June 28, 2022 Dr. Niesel informed Dr. Yoon and myself that he was having "scheduling problems" and asked for other dates in "early mid-July." The next day I offered July 8, 2022 or August 8, 9, 10 or 12 for the interview. As of today, July 13, I have not received a response. From June 22, 2022 to today, adds an additional 22 days, for a total of 111 days and counting). Further, it is worth noting that as of today, we are not aware that the SIO has approved an extension beyond the PPM requirement of 60 days.

As I have stated to you and Dr. Niesel, Dr. Yoon has had to suffer under the cloud of a misconduct/fraud investigation for over three years. He has also had to suffer under an investigation finding made in January 2020 by the prior SIC and Dr. Garg that he should be fired. At this point, we would hope that based on all the emotional, physical and practical damage Dr. Yoon and the Prakash's have suffered, you and Dr. Niesel would have worked to expedite the inquiry, or at least meet the 60 day time requirement.

What makes this worse is that it is clear that Dr. Yoon has not committed misconduct or fraud. To do so, he would have had to (1) fabricate the data or results – it is clear that did not occur; (2), falsify the data or results, which is also clear did not occur; and/or (3) commit plagiarism, which is not even alleged. At worse, Dr. Yoon committed an honest error, which as Dr. Niesel stated during Dr. Yoon's interview, he owned up to by publishing the corrigendum.

So now as the inquiry is likely to go over 120 days – twice the PPM limit – Dr. Yoon still waits for this three year horror show to end. We are not trying to be provocative by sending this letter. However, it has become a bit exasperating at the plodding nature of this inquiry after all that has preceded it and the continued damage that Dr. Yoon has had to suffer. I am aware from his



correspondence that Dr. Niesel is on vacation, but at this point, we strongly request that Dr. Yoon's interview with the SIC be scheduled during the week of August 1.

I look forward to hearing from you and please feel free to contact me at your convenience with any questions or comments.

Best regards,

Peter D. Weinstein

From: Hebbar, Rohan
To: Peter Weinstein
Cc: Sharphorn, Dan

Subject: RE: Follow up letter on Dr. Yoon inquiry

Date: Thursday, July 14, 2022 2:25:07 PM

Attachments: <u>image002.png</u>

Hi Peter,

I am in receipt of your letter. The ad hoc inquiry committee is working on scheduling a time for its interview of Dr. Yoon. Per your June 29th request, the committee is attempting to schedule the meeting on August 8th, 9th, or 10th (after 10:00am). Dr. Niesel or his designee will reach out to Dr. Yoon with you Cc'd once a date and time for the meeting is set. Lastly, regarding time limits, since the ad hoc inquiry committee is responsible for conducting the inquiry, the initiation of the inquiry occurs when the committee is given its charge and presented with the allegation. Since this occurred on June 20th, 2022, a meeting to interview Dr. Hoon in early August would not result in a failure to comply with the time for completion set out in UTMB's Policy and Procedure Manual on Integrity in Research (PPMIR) or federal law. Furthermore, as you know if Dr. Niesel, as the SIO determines that circumstances clearly warrant an extension, he may approve such extension utilizing the procedures outlined in the PPMIR.

Thanks, Rohan

Rohan Hebbar, JD, LLM
Department of Legal Affairs
Assistant Vice President
The University of Texas Medical Branch at Galveston
301 University Blvd.
Galveston, TX 77555-0171
Phone: (409) 747-8743



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From: Peter Weinstein < Peter. Weinstein@entralta.com >

Sent: Thursday, July 14, 2022 1:16 PM

To: Hebbar, Rohan <rohebbar@UTMB.EDU>

Cc: Sharphorn, Dan <dsharphorn@utsystem.edu>; Peter Weinstein

<Peter.Weinstein@entralta.com>

Subject: Follow up letter on Dr. Yoon inquiry

External Email Warning: Do not click links or open attachments unless you recognize the

sender and expect the content. <u>UTMB Email Phishing Awareness</u>

Dear Rohan,

Please see the attached letter. As stated in the letter, we are not trying to provoke you, Dr. Niesel or the SIC or cause more issues. However, the inquiry needs to start to move. The three-year process has had a material effect on Dr. Yoon and his health. The irony of this whole situation is that it is looking more like the "whistle blower" is the one who actually committed misconduct, not Dr. Yoon. Please feel free to contact me with any questions or comments. I look forward to your response.

Sincerely,

Peter

Peter D. Weinstein, Ph.D., J.D. Managing Partner



Entralta P.L.L.C., a Litigation, Intellectual Property and Business Law Firm

4500 Williams Drive
Suite 212, PMB 511
Georgetown, TX 78633
P 805-444-7865
F 805-322-4469
peter.weinstein@entralta.com
www.entralta.com

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David Niesel, PhD. Scientific Integrity Officer

5.106 Administration Building 301 University Boulevard Galveston, TX 77555-0539 O 409.772.2667 F 409.772.9598

HIGHLY CONFIDENTIAL/SENSITIVE MATERIAL

August 23, 2022

Scientific Integrity Committee Inquiry Report

RE: Jung-Hoon Yoon, PhD

1. <u>UTMB ad hoc Scientific Integrity Committee Members</u>

William Calhoun, M.D., (Professor, Department of Internal Medicine) Mahmoud Ahmed, PhD, Professor, Department of Ob/GYN Michael Kinsky, MD, PhD, Professor, Department of Anesthesiology Huey-Ming Tzeng, PhD, Professor, School of Health Professions Shinji Makino, PhD, Professor, Department of Microbiology and Immunology Grace Vargas, PhD, Department of Neuroscience and Cell Biology

2. Respondent:

Jung-Hoon Yoon, PhD, Research Scientist III, Department of Biochemistry and Molecular Biology

3. Background

In April 2019, an allegation related to the research data performed by Jung-Hoon Yoon, PhD, Research Scientist III, Department of Biochemistry and Molecular Biology ("Dr. Yoon" or the "Respondent") in Drs. Louise and Satya Prakash's lab was made by another researcher (Complainant) in the lab.

The Complainant alleges that the Western blot data used in a Supplementary Figure (S2) was from unrelated experiments and had been manipulated. The Complainant stated that they (and their mentors) became aware of this issue only after seeing the published article. This is detailed in the letter from the Complainant to the Scientific Integrity Officer ("SIO") (Exhibit C). The Complainant has since left the lab and UTMB and has returned to their home country.

The SIO interviewed the Respondent on May 19, 2022. During that interview, Dr. Yoon acknowledged that the published data was incorrect and was mistakenly included in the manuscript. Dr. Yoon also stated that some of the data provided by the Complainant is not the data included in the Supplementary data, Figure S2 of the published manuscript. The Respondent has also provided information on a Corrigendum published in the journal with the corrected data for Figure S2 with data he generated himself.

¹ The current SIO, David W. Niesel, PhD assumed the SIO role in October 2021. The allegations were reviewed by the original SIO, Nisha Garg, PhD and the UTMB Scientific Integrity Committee from 2019-2020. However, any findings and determinations made during this initial review were disregarded and a new review of the allegations commenced in 2022 with Dr. Niesel as SIO and an ad hoc Scientific Integrity Committee acting as the inquiry committee.

Upon review of the data allegations raised and the May 19, 2022 interview with the Respondent, the SIO determined that an inquiry by the *ad hoc* Scientific Integrity Committee was warranted.

4. Paper Affected by Allegations of Potential Research Misconduct

The following paper (Exhibit A) was reported as having data discrepancies (e.g. potential research misconduct):

Yoon, J. H., Johnson, R. E., Prakash, L., & Prakash, S. (2019). DNA polymerase ϑ accomplishes translesion synthesis opposite 1, N6-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development, 33(5-6), 282-287.

Support: These studies were supported by National Institutes of Health grants ES022948 and GM126087.

A Corrigendum (Exhibit B) was published in the Genes & Development journal with the corrected data for Figure S2.

5. Specific Allegations of Research Misconduct

The Complainant contacted former SIO, Nisha Garg, PhD in April 2019 with concerns about fabricated data appearing in a published article. The Complainant identified the data as Western blots they had generated and further indicated that the data had been manipulated. A detailed series of reproductions from notebooks documenting possible manipulation was provided by the Complainant (*Exhibit C*).

Allegations Concerning Fig S2 (See Exhibit C):

Fig. S2 - Panel A:

- a. In the lanes labeled NC and Polη, the bands appear to come from a notebook for another experiment that are labeled Ela and NC
- b. In the second row in Panel A, images presented are highly similar to ~40kDa bands for another experiment from a notebook page (different protein) that are labeled to be non-specific background used for Polθ. Also, the REV 1 band appears to be a mirror image.
- c. The Rev7 images appear to be highly similar to ~150kDa bands for a another protein that are labeled differently. Tubulin data appears to be from a different experiment.
- d. β-tubulin appears to be from a different cell line and experiment from 10-13-14
- e. Lane labeled siRNA; Rev -7 highly similar to ~150kDa bands from WB 5 (WAPAL).
- f. Polζ Top row appears to be mirror image from WB 7 Poli data appear to be from a blot for another protein.

Fig. S2 - Panel B:

Results appear identical to a different experiment in different lab notebook.

Fig. S2 -Panel C: NC & Rev image bands are highly similar to those from another experiment in a notebook from different experiment.

VI. List of Evidence Reviewed as Part of the Inquiry

The Complainant provided a detailed listing of data inconsistencies as part of their initial allegation. This included a detailed list of lab book entries with handwritten notes and commentary.

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Dr. Yoon provided the *ad hoc* Scientific Integrity Committee with the following information: (1) a PowerPoint slide presentation with rebutting and explanatory evidence (2) correspondence with the Genes & Development journal editor about the published Corrigendum, and (3) a data set from which the corrected Fig S2 was assembled.

VII. Individuals Interviewed as Part of the Inquiry

The Respondent, Jung-Hoon Yoon, PhD, Research Scientist III, Department of Biochemistry and Molecular Biology was interviewed by the Scientific Integrity Officer, Dr. David Niesel and the *ad hoc* Scientific Integrity committee. Dr. Yoon met with the committee on August 8, 2022 for ~1.5 hrs during which he presented slides of his data and offered explanations for the incorrect data in the original Fig. S2. He also emphasized that once questions surfaced about the data, he was sufficiently concerned about the data that he completely reproduced the entire experiment for Fig. S2 himself. Committee members asked extensive questions about the data, record keeping and his data treatment procedures.

VIII. SIC's Recommendation on Whether to Conduct an Investigation Into these Allegations of Research Misconduct

The *ad hoc* Scientific Integrity Committee met on August 8, 2022 to interview Dr. Yoon and to review the results of the Inquiry. Based upon Inquiry evidence, the *ad hoc* Scientific Integrity Committee voted to move this matter to Investigation. The *ad hoc* Scientific Integrity Committee concluded that the data presented in Figure S2 of the published paper was problematic and appeared to involve mislabeling, inconsistent record keeping and was concerned about Dr. Yoon's inability to produce the Western blots for the original Fig S2. Overall, this did not adequately support the Respondent's view that this was an honest mistake or oversight. The committee voted in favor of moving forward with an investigation.

IX. Evidence Supporting the SIC's Recommendation to Conduct an Investigation

There were concerns about the data used to assemble Fig S2. There were issues with the labeling of images and mismatching of the data for the Figure. The Respondent could not produce the original data that was used to construct the Figure. He stated that there are no records that would identify the raw data used in the Figure. There was also a lack of details as to the specifics of how the experiment was conducted. The respondent stated that he was under high pressure and in a hurry at the time and the incorrect data being utilized was an honest mistake. The committee believes there is a need for a more thorough investigation as there was a lack of rigor in the approach to assembling this data for this supplementary Figure. Further investigation would help determine if there was falsification of the original data used.

The committee was concerned about the lack of molecular weight markers in the corrected Fig. S2. While Dr. Yoon stated that his practice was to include these on each side of the experimental lanes, this could be confirmed by viewing the original gel/Western images for the S2 sub-figures.

X. Complainant and Respondent Comments

The Complainant who provided the allegations has left the university and returned to their home country. The SIO has not obtained additional comments from the Complainant.

The Respondent's comments, if any, will be presented in Exhibit E of this report.

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David W. Niesel, PhD
Scientific Integrity Officer
Adjunct Professor, Microbiology & Immunology
University of Texas Medical Branch, Galveston TX

Attachments:

Exhibit A: Genes & Development, 33(5-6), 282-287 article as published

Exhibit B: Corrigendum published in the journal with the corrected data for Figure S2.

Exhibit C: Communication and Notes from Complainant

Exhibit D: Presentation by Dr. Yoon at SIO interview on May 19, 2022

Exhibit E: Respondent's comments to the draft Inquiry Report

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RESEARCH COMMUNICATION

DNA polymerase θ accomplishes translesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satya Prakash

Department of Biochemistry and Molecular Biology, University of Texas Medical Branch at Galveston, Galveston, Texas 77555, USA

Here we show that translesion synthesis (TLS) opposite 1, N⁶-ethenodeoxyadenosine (εdA), which disrupts Watson-Crick base pairing, occurs via Pol₁/Pol₂-, Rev1-, and Polθdependent pathways. The requirement of Pol₁/Polζ is consistent with the ability of Poli to incorporate nucleotide opposite εdA by Hoogsteen base pairing and of Polζ to extend synthesis. Rev1 polymerase and Polθ conduct TLS opposite EdA via alternative error-prone pathways. Strikingly, in contrast to extremely error-prone TLS opposite εdA by purified Polθ, it performs predominantly errorfree TLS in human cells. Reconfiguration of the active site opposite εdA would provide Pol θ the proficiency for error-free TLS in human cells.

Supplemental material is available for this article.

Received September 10, 2018; revised version accepted January 8, 2019.

The 1, N⁶-ethenodeoxyadenosine (εdA) adduct is formed in DNA through interaction with aldehydes derived from lipid peroxidation and by exposure to chemical carcinogens such as vinyl chloride. Lipid peroxidation is a normal chain reaction process that initiates from the oxidation of polyunsaturated fatty acids in cell membranes and results in the formation of a variety of highly reactive aldehydes, including acrolein, malonaldehyde, and trans-4-hydroxy-2-nonenal (HNE). Enals such as HNE undergo further oxidation reactions to form epoxyaldehydes and the reaction of epoxyaldehyde with DNA generates the εdA adduct (Chung et al. 1999; Luczaj and Skrzydlewska 2003)

The εdA adduct is highly inhibitory to synthesis by replicative DNA polymerases (Pols) because the exocyclic ring between the N1 and N6 positions of εdA impairs the Watson-Crick (W-C) edge of adenine (Supplemental Fig. S1). The ability of the Poli active site to push template purines into a syn conformation provides a mechanism by which this polymerase can insert nucleotides opposite DNA lesions which disrupt W-C base pairing. Biochemi-

[Keywords: DNA polymerase θ; εdA lesion; Hoogsteen base pairing; translesion synthesis]

Corresponding author: loprakas@utmb.edu

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cal studies have shown that while Poli incorporates a T correctly opposite the \(\text{sdA} \) adduct, it also incorporates a C with an about one fourth efficiency of that of T incorporation (Nair et al. 2006). Crystal structures of PoliεdA·dTTP and Pol-εdA·dCTP ternary complexes show that similar to nonadducted A, the edA adduct adopts a syn conformation in the Poli active site and its "Hoogsteen" edge" participates in hydrogen bonding with the incoming dTTP or dCTP (Nair et al. 2006). Since Poli is highly inefficient at extending synthesis from the T or C inserted opposite εdA, the extension reaction would require another TLS Pol and biochemical studies have indicated that Polζ can extend synthesis from the edA·dT or edA·dC base pair (Nair et al. 2006).

Here we identify the TLS Pols that promote replication through the EdA adduct in human cells and show that replication through this adduct is mediated via three genetic pathways. As expected from biochemical and structural studies, Polι and Polζ function together in one pathway; however, contrary to biochemical and structural observations indicating a proficiency of Poli for misincorporating C opposite εdA, the Poli/Polζ pathway mediates highly error free TLS opposite this adduct in human cells. Rev1 polymerase activity contributes to a low level of TLS that is mutagenic; in this role, Rev1 functions independent of its scaffolding role with Poli in the Polι/Polζ pathway. Polθ, a member of A-family Pols, promotes replication through εdA via a third pathway. Although biochemical studies show that purified Pol0 conducts highly error-prone TLS by incorporating an A opposite εdA, in human cells Polθ mediates predominantly error-free TLS opposite this adduct. We discuss the implications of this marked discrepancy and suggest that opposite DNA lesions such as εdA, Polθ active site is actively reconfigured in human cells to carry out predominantly error-free TLS.

Results and Discussion

Requirement of Poli/Pol ζ and Pol θ for Replication through the εdA adduct in human cells

To identify the TLS Pols required for replicating through the EdA adduct, we analyzed the effects of siRNA depletion of TLS Pols individually and in combinations (Supplemental Fig. S2) on TLS frequencies resulting from replication through the lesion present on the leading or the lagging strand template of the SV40 based duplex plasmid. TLS opposite the εdA adduct carried on the leading strand template in normal human fibroblasts (HFs) and treated with control (NC) siRNA occurs with a frequency of ~25% and TLS frequency was not affected in cells depleted for Poln or Polk, indicating that these Pols play no significant role in TLS opposite this adduct (Table 1). In contrast, TLS frequency was reduced to ~14% in Poli-depleted cells. A similar reduction in TLS frequency occurred upon depletion of the Rev3 or the Rev7 subunit of Polζ, and depletion of Polθ reduced TLS frequency to

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~17% (Table 1). The observation that TLS frequency remained the same in cells codepleted for Poli with Rev3 or Rev7 as that in cells depleted for any of these Pols alone (Table 1) indicated that Poli and Polζ function together in one TLS pathway. In contrast, codepletion of Poli with Polθ or of Rev3 or Rev7 with Polθ caused a drastic reduction in TLS frequency to ~4% (Table 1), indicating that Polθ functions independently of Poli and Polζ and that TLS through the εdA adduct is mediated by two separate pathways dependent on either Poli/Polζ or Polθ. We verified this conclusion for TLS opposite εdA present on the lagging strand template (Table 1).

Noncatalytic and catalytic roles of Rev1 in TLS opposite εdA

In human cells, Rev1 functions as an indispensable noncatalytic scaffolding component of Y-family Pols (Yoon et al. 2015). Since ~15% of total TLS persists in HFs codepleted for Pol θ with Pol $_{1}$ or Pol ζ (Table 1), we considered the possibility that in addition to its role as a noncatalytic scaffolding component of Poli in the Poli/Pol\(\zeta\) pathway, Rev1 contributes to TLS as a DNA polymerase and in this role it functions independently of Poli. To test for this possibility, we first determined whether there was evidence for Poli-dependent and Poli-independent roles of Rev1, and analyzed TLS opposite ϵdA in wild-type (WT), Rev1^{-/-} (Yoon et al. 2015), and $Pol\theta^{-/-}$ (Yoon et al. 2019) mouse embryonic fibroblasts (MEFs) depleted for different TLS Pols (Supplemental Fig. S2; Supplemental Table S1). In WT MEFs, TLS opposite edA occurs with a frequency of \sim 22% and TLS is reduced to \sim 8% in Rev1^{-/-} MEFs treated with NC siRNA or depleted for Poli or Pol². The epistasis of Rev1 over Polι in the Polι/Polζ pathway is consistent with a scaffolding role of Rev1 with Poli. To unravel the Poli-independent role of Rev1, we examined TLS in $Pol\theta^{-/-}$ MEFs depleted for Poli or Pol ζ , since then only the Poli/Polζ-independent role of Rev1 would remain functional. Our observation that TLS frequency is reduced to ~3.5% in Pol $\theta^{-/-}$ MEFs depleted for Poli or Pol ζ strongly suggested that this residual TLS is mediated by the Poli/ Pol\(\zeta\)-independent role of Rev1. Furthermore, the almost abolition of TLS in $Pol\theta^{-/-}$ MEFs depleted for Rev1 or in Rev1^{-/-} MEFs depleted for Polθ provided confirmatory evidence for the Poli-dependent and Poli-independent Rev1 roles.

To determine whether Rev1 polymerase function was required for its Poli-independent role, we examined TLS in HFs expressing siRNA-sensitive WT Revl or the siRNA-resistant form of either the WT or the catalytically inactive Rev1 D570A, E571A mutant. TLS in cells depleted for Rev1 and carrying the vector control or the siRNAsensitive WT Rev1 was reduced to ~9% as compared to ~25% in control siRNA-treated cells (Supplemental Table S2). Expression of the siRNA-resistant WT Rev1 restored TLS frequency nearly to normal levels (~23%), while expression of siRNA-resistant D570A, E571A catalytic mutation reduced TLS to ~20% (Supplemental Table S2). This reduction in TLS frequency closely resembles the reduction in TLS frequency that occurs in HFs codepleted for Poli and Pol θ (Table 1) or in Pol $\theta^{-/-}$ MEFs depleted for Poli (Supplemental Table S1). This result suggested that Rev1 polymerase activity accounts for a small proportion of total TLS opposite edA and that this TLS operates independently of Rev1's scaffolding role with Poli, which will remain intact in Rev1 catalytic mutant. To further ascertain the contribution of Rev1 polymerase activity to TLS, we examined the effect of Rev1 catalytic mutation on TLS opposite εdA in Rev1^{-/-} MEFs. In Řev1^{-/-} MEFs expressing WT Rev1, TLS occurred at a frequency of ~19% and TLS was reduced to ~16% in these MEFs expressing catalytic mutant Rev1 (Supplemental Table S3). This result reinforces the evidence that Rev1 polymerase activity contributes to a relatively small proportion of total TLS opposite edA. Overall, from analyses of TLS in WT HFs, WT MEFs, Rev1^{-/-} MEFs, and Pol θ ^{-/-} MEFs, we conclude that TLS opposite EdA is mediated by two major Polι/Polζ- and Polθ-dependent pathways, respectively, and by a relatively minor Rev1 polymerase-dependent pathway (Table 1; Supplemental Tables S1-S3).

Requirement of Pol θ polymerase activity for TLS opposite εdA in human cells

Human Polθ is a 290 kDa protein comprised of an N-terminal ATPase/helicase domain, a large central domain, and a C-terminal polymerase domain that shares homology with A-family DNA Pols such as *Escherichia coli*

Table 1. Effects of siRNA knockdown of TLS polymerases on the replicative bypass of the εdA lesion carried on the leading or lagging strand template in HFs (GM637)

siRNA		Leading strand	Lagging strand				
	Number of Kan ⁺ colonies	Number of blue colonies among Kan ⁺	TLS (%)	Number of Kan ⁺ colonies	Number of blue colonies among Kan+	TLS (%)	
NC	659	168	25.5	502	116	23.1	
Poln	623	146	23.4	460	108	23.5	
Polĸ	658	161	24.5	403	96	23.8	
Polı	589	80	13.6	367	48	13.1	
Rev3	615	82	13.3	352	38	10.8	
Rev7	308	40	13.0	401	45	11.2	
Polθ	612	102	16.7	428	60		
Polı + Rev3	623	78	12.5	394	51	12.9	
Polı + Rev7	412	49	11.9	294	34	11.6	
Polι + Polθ	674	26	3.9	408	16	3.6	
Rev3 + Polθ	236	9	3.8	426	18	4.2	
Rev7 + Polθ	405	15	3.7	314	11	3.5	

Yoon et al.

Pol I (Yousefzadeh and Wood 2013). We have shown previously that Polθ comprised of residues 1708–2590 performs proficient TLS opposite thymine glycol in human cells Yoon et al. 2014) and provide evidence here that Pol0 (1708–2590) is sufficient for TLS opposite εdA. Whereas TLS in control siRNA-treated HFs occurs with a frequency of ~25%, this frequency declines to ~15% in cells depleted for genomic Polθ and carrying either an empty vector or one expressing siRNA-sensitive WT Polθ (1708–2590) (Supplemental Table S4). Expression of an siRNA-resistant WT Polθ (1708–2590), however, restores normal TLS levels in HFs depleted for genomic Polθ, confirming that the C-terminal polymerase domain is sufficient for Polθ-dependent TLS opposite the εdA lesion. TLS was reduced to ~15% in HFs expressing the siRNAresistant Polθ (1708–2590) D2540A, E2541A mutant protein defective in DNA synthesis, indicating that Polθ polymerase activity is required for its role in TLS opposite εdA (Supplemental Table S4). We confirmed the requirement of Polθ polymerase activity for TLS opposite εdA in $Pol\theta^{-/-}$ MEFs (Supplemental Table S5).

The $Pol_i/Pol\zeta$ pathway conducts error-free TLS opposite εdA in human cells

TLS opposite εdA incurs a high level of mutagenesis (Table 2). In control (NC) siRNA-treated cells, $\sim 16\%$ of Kan^+ blue colonies derived from TLS opposite εdA carried on the leading strand template harbored a mutation that resulted from the incorporation of primarily a C, but also of an A or a G opposite εdA . Of the incorrect nucleotides, C was incorporated at a frequency of $\sim 11\%$, whereas the A and G nucleotides were incorporated at a combined frequency of $\sim 5\%$ (Table 2). As expected from the lack of requirement of Pol η or Pol κ for TLS opposite εdA , the spectrum and frequency of mutagenic TLS opposite this adduct was unchanged upon their depletion. Importantly, depletion of Pol η , Rev3, or Rev7 raised the frequency of mutagenic

TLS to ~27% and Pol θ depletion reduced mutagenic TLS to ~10% (Table 2). These results as well as analyses of mutagenic TLS opposite ϵ dA carried on the lagging strand template indicated that Pol ℓ Pol ℓ -dependent TLS operates in an error-free manner, whereas Pol θ -mediated TLS is error-prone.

To get an estimate of the overall contributions of the Polı/Polζ and Polθ pathways to error-free and mutagenic TLS, respectively, we pooled the mutation data for the two DNA strands. Overall, mutagenic TLS opposite εdA in WT HFs occurs with a frequency of ~14%, this frequency rises to ~27% in cells depleted for Polι or Polζ, and declines to ~9% in Polθ-depleted cells (Table 2). Whereas incorporation of C occurs with a frequency of ~10% in control siRNA-treated cells, it rises to ~20% in cells depleted for Polι or Polζ and declines to ~5% in Polθ-depleted cells. These data suggested that Polθ-mediated TLS contributes to C misincorporation opposite εdA and raised the possibility that Rev1 polymerase activity contributes to mutagenic TLS that persists in Polθ-depleted cells.

The DNA polymerase activities of $Pol\theta$ and Rev1 account for error-prone TLS opposite εdA

To test whether the Rev1 polymerase activity contributes to mutagenic TLS and to determine whether Rev1 and Pol θ polymerase activities provide alternative routes of mutagenic TLS, we analyzed the effects of mutations in active site residues in their polymerase domains on mutagenic TLS opposite ϵ dA. As shown in Table 3, in Pol θ -depleted cells expressing siRNA-sensitive WT Pol θ , \sim 10% of TLS products harbor mutations, and the frequency of mutagenic TLS rises to \sim 16% in cells expressing siRNA-resistant WT Pol θ , suggesting that \sim 6% of mutations result from Pol θ -mediated TLS. Expression of the siRNA-resistant catalytic mutant of Pol θ also reduced mutation frequency to \sim 10%, indicating that Pol θ 's polymerase activity is required for its role in mutagenic TLS. In Rev1-depleted cells

Table 2. Effects of siRNA knockdowns of TLS polymerases on mutation frequencies and nucleotides inserted opposite εdA carried on the leading or lagging strand template in HFs (GM637)

-dA containing DNIA	siRNA	Number of <i>Kan</i> ⁺ blue colonies sequenced	Nucleotide inserted				
edA-containing DNA strand			A	G	С	T	Mutation frequency (%
Leading strand	NC	220 (35) ^a	7	3	25	185	15.9
	Polη	164 (25)	3	2	20	139	15.2
	Polκ	166 (26)	3	2	21	140	15.7
	Polı	160 (41)	5	6	26	119	25.6
	Rev3	260 (68)	13	8	47	192	26.2
	Rev7	96 (28)	5	2	21	68	29.2
	Polθ	196 (19)	3	5	11	177	9.7
Lagging strand	NC	170 (20)	2	2	16	150	11.8
	Polη	96 (11)	2	2	7	85	11.5
	Poli	188 (50)	5	1	44	138	26.6
	Rev3	96 (26)	4	0	22	70	27.1
	Rev7	104 (32)	5	0	27	72	30.8
	Polθ	180 (13)	1	3	9	167	7.2
Leading or lagging strand	NC	390 (55)	9	5	41	335	14.1
	Polı	348 (91)	10	7	74	257	26.1
	Rev3	460 (126)	22	8	96	334	27.4
	Rev7	200 (60)	10	2	48	140	30.0
	$Pol\theta$	376 (32)	4	8	20	344	8.8

^aNumber of colonies where TLS occurred by insertion of a nucleotide other than T are shown in parentheses.

Table 3. Effect of catalytically active (WT) Polθ, catalytically inactive D2540A E2541A mutant Polθ, catalytically active (WT) Rev1, or catalytically inactive D570A E571A mutant Rev1 on mutation frequencies and nucleotides inserted opposite εdA carried on the leading strand DNA template in HFs (GM637)

	Vector expressing	Number of Kan ⁺ blue colonies sequenced	Nucleotide inserted				Martin	Turner and TI Consideration
siRNA			A	G	С	Т	Mutation frequency (%)	Error-prone TLS pathway that remains active
Polθ	WT-Polθ	96 (10) ^a	2	1	7	86	10.4	Rev1 Pol
Polθ	siR ^b -WT-Polθ	96 (15)	3	1	11	81	15.6	Rev1 Pol, Polθ
Polθ	siR-mutant Polθ	90 (9)	2	0	7	81	10.0	Rev1 Pol
Rev1	WT-Rev1	96 (7)	2	1	4	89	7.3	Polθ
Rev1	siR-WT-Rev1	96 (16)	3	2	11	80	16.7	Rev1 Pol, Polθ
Rev1	siR-mutant Rev1	88 (7)	3	0	4	81	8.0	Polθ
Rev1 + Polı	siR-mutant Rev1	80 (6)	2	0	4	74	7.5	Polθ
$Rev1 + Pol\theta$	siR-mutant Rev1	96 (0)	0	0	0	96	0.0	Neither

^aNumber of colonies where TLS occurred by insertion of a nucleotide other than T are shown in parentheses.

expressing siRNA-sensitive WT Rev1, mutagenic TLS occurs at a frequency of \sim 7%, and expression of the siRNAresistant WT Rev1 raises the frequency of mutagenic TLS to ~17% (Table 3). This result indicated the requirement of Rev1 for mutagenic TLS. To establish that Rev1 polymerase activity was required for mutagenic TLS and that Rev1 functions in this role independent of Poli, we expressed siRNA-resistant Rev1 catalytic mutant in Rev1-depleted cells or in cells codepleted for Rev1 and Poli (Table 3, items 6 and 7). In both cases, mutagenic TLS was reduced to 8%, confirming the Poli-independent role of Rev1 polymerase in mutagenic TLS. The observation that codepletion of Rev1 and Pol θ in cells expressing siRNA-resistant Rev1 catalytic mutant causes a complete inhibition of mutagenic TLS (Table 3, last item) supports the conclusion that Rev1 polymerase and Polθ polymerase activities provide alternative routes for mutagenic TLS opposite εdA (Table 3). Since no mutations occur in cells lacking Polθ and Rev1 polymerase activity but retaining the Rev1 scaffolding function, where only the Pol₁/Polζ pathway would remain functional, Polι/Polζ-dependent TLS must operate in an error-free manner (Table 3, last item).

To further ascertain the contributions of Rev1 polymerase-dependent and Polθ-dependent pathways to mutagenic TLS and to verify the requirement of Poli for error-free TLS in the Pol_ι/Polζ pathway, we analyzed the mutation spectrum of TLS products in WT and $Pol\theta^{-/-}$ MEFs, and in Rev1^{-/-} MEFS lacking or expressing the catalytic mutant Rev1 protein (Supplemental Table S6). The effects of Polθ and Rev1 knockouts on the frequency and mutation spectrum of TLS products are remarkably similar to that in HFs depleted for these Pols (Table 3) and the results that no mutations are recovered in Rev1^{-/-} MEFs expressing the catalytic mutant Rev1 protein and depleted for Polθ (Supplemental Table S6) provide confirmatory evidence that Rev1 polymerase and Polθ provide alternate pathways of mutagenic TLS, and that the Polι/Polζ pathway, which would remain functional in these MEFs, operates in an error-free manner.

Biochemical analysis of Pol θ polymerase activity for TLS opposite εdA

For these studies, we examined DNA synthesis by Pol θ across from either an undamaged A or ϵ dA. Whereas oppo-

site an undamaged A template Pol θ inserts a T but also a C or a G (Fig. 1, lanes 1–5), opposite &A Pol θ primarily inserts an A (Fig. 1, lanes 9,4,19). Although Pol θ can insert each of the four dNTPs opposite &A, importantly, in the presence of all four dNTPs, dATP is preferentially inserted (Fig. 1, lane 10). Since dATP was preferentially incorporated opposite &A in a template in which the downstream 5′ template nucleotide was a T residue, we determined whether Pol θ used a frameshift mechanism to incorporate dATP opposite the downstream template T rather than opposite &A. To examine this, we used templates containing edA that harbor either an A or a G as the next templating

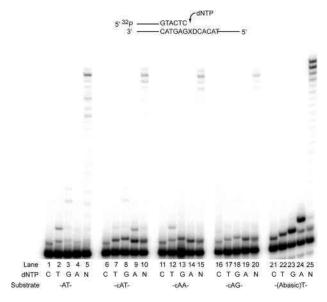


Figure 1. Nucleotide incorporation opposite A or ϵ dA by Pol θ . 0.5 or 5 nM Pol θ was incubated with 10 nM DNA substrate and 25 µM of either dGTP, dATP, dTTP, dCTP, or all four dNTPs for 5 min at 37° C. Reactions containing a single or all four dNTPs [N] are indicated. The DNA substrate used in lanes 1-5 harbor undamaged template A at the primer terminus, and reactions contained 0.5 nM Pol θ . The substrate in lanes 6-20 harbored ϵ dA at the primer terminus followed by either T (lanes 6-10), A (lanes 11-15), or G (lanes 16-20) residue, indicated by D in the template sequence. Synthesis opposite an abasic site is shown in lanes 21-25. Reactions in lanes 6-25 were all carried out with 5 nM Pol θ . X in the template sequence indicates the position of undamaged A, ϵ dA, or an abasic site.

^b(siR) siRNA-resistant.

Yoon et al.

residue downstream from the lesion (Fig. 1, lanes 11–20). In each case, an A was the best incorporated nucleotide opposite ϵdA , suggesting that Pol θ is not frameshifting the template and using the downstream nucleotide, for if it were, then the pattern of insertion would be different for each substrate and a preference for the W–C partner of the downstream nucleotide would be observed.

Pol θ exhibits a high proficiency for replicating through an abasic site by inserting an A opposite it and by extending synthesis (Fig. 1, lanes 24,25; Seki et al. 2004). Although Pol θ is more efficient in performing TLS opposite an abasic site than opposite ϵ dA, the similar pattern of nucleotide incorporation opposite the two DNA lesions (Fig. 1) suggests that the ϵ dA adduct becomes extrahelical and Pol θ incorporates an A opposite an abasic site-like mode.

Biochemical analysis of Rev1 polymerase activity for TLS opposite εdA

Rev1 specifically incorporates dCTP opposite template G (Nelson et al. 1996: Haracska et al. 2002). In the Rev1 active site, template G, and the incoming dCTP do not pair with each other; instead, the template G residue is evicted from the DNA helix and makes hydrogen bonds via its Hoogsteen edge with the amino acids in the G loop of Rev1, while an Arg residue in Rev1 forms hydrogen bonds with the incoming dCTP (Nair et al. 2005; Swan et al. 2009). Rev1 favors nucleotide incorporation opposite template G over other nucleotides because the G loop makes specific hydrogen bonds with the Hoogsteen edge of templating G. Incorporation of dCTP opposite template A is much less favorable, likely due to the presence of the N⁶ H-bond donor on adenine which would sterically hinder binding by the G loop. Since εdA lacks the N⁶ amino group (Supplemental Fig. S1A), it would not sterically clash with the G loop. Accordingly, we found that under identical conditions, nucleotide incorporation opposite \(\varepsilon A \) is better than opposite template A (Supplemental Fig. S3). In fact, yeast Rev1 incorporates dCTP opposite edA with a catalytic efficiency only approximately fivefold less than template G, whereas opposite template A, yeast Revl is ~200-fold less efficient (data not shown). This proposed better binding of \(\epsilon\) dA by the Rev1 G loop over template A would also account for the incorporation of dGTP and dTTP mispairs opposite edA that is not observed opposite template A (Supplemental Fig. S3, lanes 1,3 vs. 6,8,11,13,16,18). Since in the presence of all four dNTPs (Supplemental Fig. S3, lanes 10,15,20), Rev1 preferentially incorporates dCTP, dCTP is incorporated opposite edA with the highest catalytic efficiency.

Pathways for replicating through εdA in human cells

Based upon our observations in HFs, and in WT, $Pol\theta^{-/-}$, $Rev1^{-/-}$ MEFs, we conclude that replication through the ϵdA adduct is mediated via two Rev1-dependent TLS pathways in which Rev1 functions as a noncatalytic component of Poli in the Poli/Pol ζ pathway and as a DNA polymerase that functions independently of the Poli/Pol ζ pathway and via a third pathway dependent on Pol θ (Supplemental Fig. S4). Poli/Pol ζ -dependent TLS operates in an error-free manner, Rev1 polymerase activity makes a relatively minor contribution to TLS and it acts in an error-prone manner, and Pol θ polymerase activity provides the alternative route of mutagenic TLS.

Role of $Poli/Pol\zeta$ -dependent TLS in error-free replication through εdA in human cells

Although structural studies have shown that Poli can accommodate dTTP or dCTP opposite edA via Hoogsteen base pairing, and biochemical studies have shown that Poli incorporates a T opposite edA with only an approximately fourfold higher catalytic efficiency than a C (Nair et al. 2006), our genetic studies reveal that Poli-dependent TLS opposite this lesion operates in an error-free manner in human cells. In the Polι active site, εdA is pushed into a syn conformation and it forms a Hoogsteen base pair with the incoming T or C residue (Nair et al. 2006). While the ability of Polito push the adduct into the syn conformation explains its proficiency for TLS opposite εdA, it does not explain how Poli avoids C incorporation in human cells. To explain the high fidelity of Poli opposite EdA in human cells, we suggest that TLS Pols function as a component of a multiprotein ensemble and that their fidelity is actively regulated in such an ensemble by protein-protein interactions and posttranslational modifications. A similar mechanism would account for predominantly errorfree replication by TLS Pols through other DNA lesions (Yoon et al. 2009, 2010, 2017, 2018; Conde et al. 2015).

Reconfiguration of Pol θ active site opposite εdA in human cells

Similar to other A family Pols, Pol θ incorporates nucleotides opposite undamaged A, G, C, or T templates via W–C base pairing. Since ϵdA disrupts W–C base pairing, purified Pol θ could replicate through this adduct by pushing it out of the DNA helix into an abasic-like mode, then inserting an A opposite the adduct site and extending synthesis. The feasibility of this scenario is suggested from the proficient ability of Pol θ to replicate through an abasic site where it inserts an A opposite the abasic site and then extends synthesis. Structural studies with Pol θ have verified its ability to insert an A opposite an abasic site [Zahn et al. 2015].

Even though Polθ contributes to error-prone TLS opposite εdA in human/mouse cells, in both HFs and MEFs, it incorporates a T at a frequency of ~92%, a C at ~5%, and an A at ~3% (Table 3; Supplemental Table S6). Thus in spite of the propensity of purified Pol θ for incorporating an A opposite εdA, Polθ-mediated TLS opposite this adduct is predominantly error-free in human cells. Polθ could accomplish this by pushing edA into a syn conformation and by forming a Hoogsteen base pair with the incoming T. The low frequency of C insertion could also occur by similar means. Although in its potential to form a Hoogsteen base pair between edA in syn conformation and an incoming T or C in *anti* conformation Polθ would resemble Poli, the two Pols would differ in a number of ways. Poli has a preformed active site which enables it to similarly position an undamaged A or an edA in the syn configuration; hence, Poli would adopt a similar mechanism for performing TLS in human cells as it portrays in biochemical assays. In striking contrast, Polθ would need to adopt entirely different means for conducting TLS opposite edA in human cells than those adopted by purified Pol θ .

To explain the adoption of different TLS mechanisms by Polθ in human cells vs in biochemical assays with purified enzyme, we suggest that Polθ functions in TLS in human cells as a component of a multiprotein ensemble and that protein–protein interactions and posttranslational

High fidelity translesion synthesis by Pol0

modifications in that ensemble actively modulate Pol θ active site such that the ϵdA adduct is pushed and stabilized in a syn conformation, allowing for Hoogsteen base pairing primarily with the T. Thus, whereas protein–protein interactions in the Pol θ -containing multiprotein ensemble would actively reconfigure Pol θ active site for Hoogsteen base pairing opposite ϵdA enabling it to conduct relatively high fidelity TLS in human cells, in Pol θ with its preformed active site, the overall mechanism of Hoogsteen base pairing would stay the same in the multiprotein ensemble in human cells as with purified Pol but its fidelity opposite ϵdA will be greatly enhanced in human cells.

Materials and methods

Construction of edA plasmid vectors and translesion synthesis assays

The 16-mer oligonucleotides containing ϵdA , purchased from the Midland Certified Reagent Company, Inc., and the in-frame target sequence of lac Z' gene in the resulting vectors are shown in Supplemental Figure S1B. The WT kanamycin gene (Kan*) was placed on the same DNA strand as ϵdA and lacz' in this DNA strand is in-frame and functional for β -gal. The opposite DNA strand harbors an SpeI restriction site containing a +1 frameshift, which makes it nonfunctional for β -gal. This DNA strand carries the Kan- gene. The detailed methods for construction of lesion containing SV40 duplex plasmid, for assays for translesion synthesis, and for mutation analyses of TLS products have been published previously (Yoon et al. 2009, 2010).

Protein expression and purification

Rev1 core (amino acid residues 330–883) and Polθ core (amino acid residues 1708–2590) proteins were each expressed and purified from yeast as fusion proteins harboring an N-terminal Glutathione-S transferase (GST) tag as described (Johnson et al. 2006). Rev1 and Polθ proteins were expressed from plasmids pBJ1228 and pPOL507, respectively. The GST tags were removed by prescisson protease during purification.

DNA polymerase assays

Proteins were assayed using the standard DNA polymerase reaction conditions (Johnson et al. 2006). The DNA substrate consisted of the 52mer temple 5′-TTCGTATAATGCCTACACDXGAGTACCGGAGCATCGTCGT GACTGGGAAAAC-3′, where D indicates either G, A, or T and X indicates either an undamaged A or sdA annealed to the 32mer ^{32}P radiolabeled primer 5′-GTTTTCCCAGTCACGACGATGCTCCGGTACTC-3′. Reactions (5 μ L), carried out for 5 min at 37°C, contained 10 nM DNA substrate, 25 μ M dNTP and protein concentrations as indicated in the figure legends. Reaction products were separated by 15% TBE PAGE containing 8 M urea as described, and visualized by phosphorimaging on a Typhoon FLA 7000 (GE Healthcare).

Acknowledgments

These studies were supported by National Institutes of Health grants ES022948 and GM126087.

Author contributions: J.H.Y. performed the genetic experiments and analyzed the data; R.E.J. performed biochemical experiments and analyzed the data; L.P. and S.P. designed and coordinated the study; J.H.Y., R.E.J., L.P., and S.P. wrote the paper.

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CORRIGENDUM

Genes & Development 33: 282–287 (2019)

Corrigendum: DNA polymerase θ accomplishes translesion synthesis opposite $1,N^6$ -ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satya Prakash

In Supplemental Figure S2 in the above article, we have been unable to confirm that the Western blots in panels A–C were assembled correctly. Because of our concerns about the accuracy of the data in the Western blots, we are presenting a new set of verified experiments in the new Supplemental Figure S2, which can be found in the Revised Supplemental Material online. This change in no way affects any of the results or conclusions of this study. The authors apologize for this error.

doi: 10.1101/gad.334946.119



DNA polymerase θ accomplishes translesion synthesis opposite 1,N⁶ -ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, et al.

Genes Dev. 2019, **33:** originally published online February 26, 2019 Access the most recent version at doi:10.1101/gad.320531.118

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Related Content

Corrigendum: DNA polymerase accomplishes translesion synthesis opposite 1,N6-ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, et al.

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Use CRISPRmod for targeted modulation of endogenous gene expression to validate siRNA data



Methods, list of antibodies, and the compilation of corrected Figure S2 by Jung-Hoon Yoon

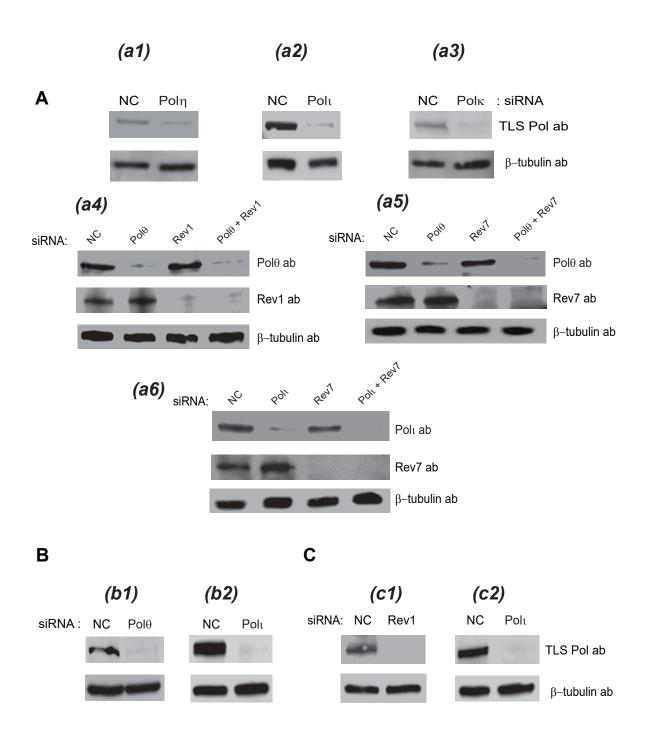
Experimental procedures

Western blot analysis for siRNA depletion of TLS Pols in HFs or MEFs

48h after siRNA transfection, cells were washed with PBS buffer and lysed with RIPA buffer (1x PBS, 1% IP-40, 0.5% sodium deoxycholate, 0.1% SDS). 30μg of prepared cellular extracts were separated on a 10% SDS-polyacrylamide gel and transferred to a PVDF membrane (Bio-rad). The membranes were probed with antibodies against Polη (rabbit polyclonal antibody against full length of human Polη), Polı (Bethyl Laboratories, A301-304A), Polκ (Bethyl Laboratories, A301-977A), Rev1 (Abcam, Ab5088), Rev7 (BD Biosciences, 612266), or Polθ (Abcam, Ab80906) followed by appropriate secondary antibodies conjugated with horseradish peroxidase. The signals were detected using ECL-Plus (GenDEPOT) or SuperSignal West Femto reagent (Thermo Scientific). For the loading control, anti-β-tubulin antibody (Santa Cruz Biotechnology, sc-5274) was used.

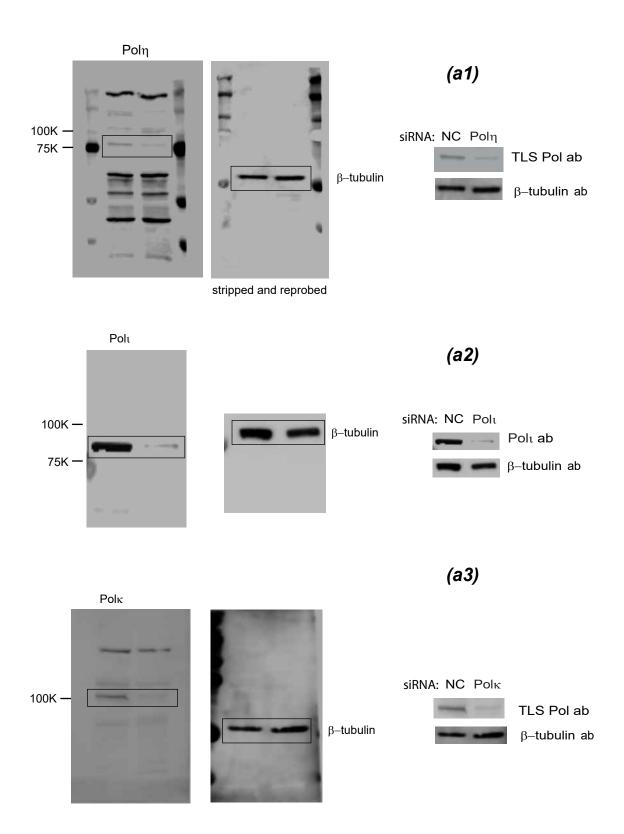
Antibody list

Antibody	SOURCE	IDENTIFIER
Rabbit polyclonal anti-Pol eta	Lab Stock (against full length Poleta)	N/A
Rabbit polyclonal anti-Pol lota	Bethyl Laboratories	A301-304A
Rabbit polyclonal anti-Pol Kappa	Bethyl Laboratories	A301-977A
Rabbit polyclonal anti-Pol theta	Abcam	Ab80906
Goat polyclonal anti-Rev1	Abcam	Ab5088
Mouse monoclonal anti-Rev7	BD Biosciences	612266
Mouse monoclonal anti-β tubulin (D-10)	Santa Cruz Biotechnology	sc-5274
Goat anti-rabbit IgG-HRP	Santa Cruz Biotechnology	sc-2004
Goat anti-mouse IgG-HRP	Santa Cruz Biotechnology	sc-2005
Rabbit anti-goat IgG-HRP	Santa Cruz Biotechnology	sc-2768



New Supplemental Figure S2 (marked for easy linking to ai files)

Normal HFs (GM637)



Supplemental Figure S2 (parts a1 to a3)

EXHIBIT "RR"

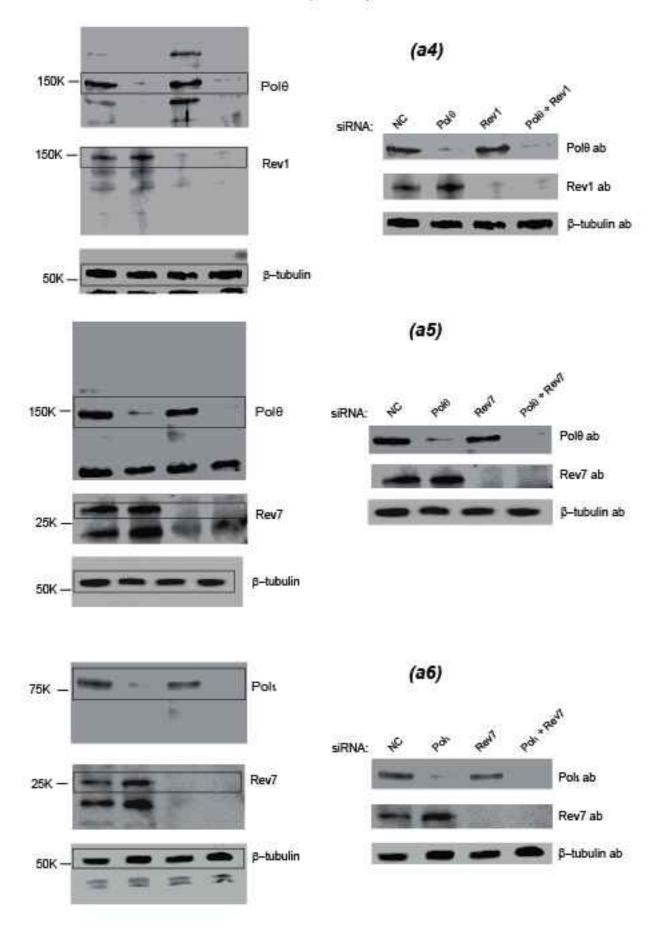
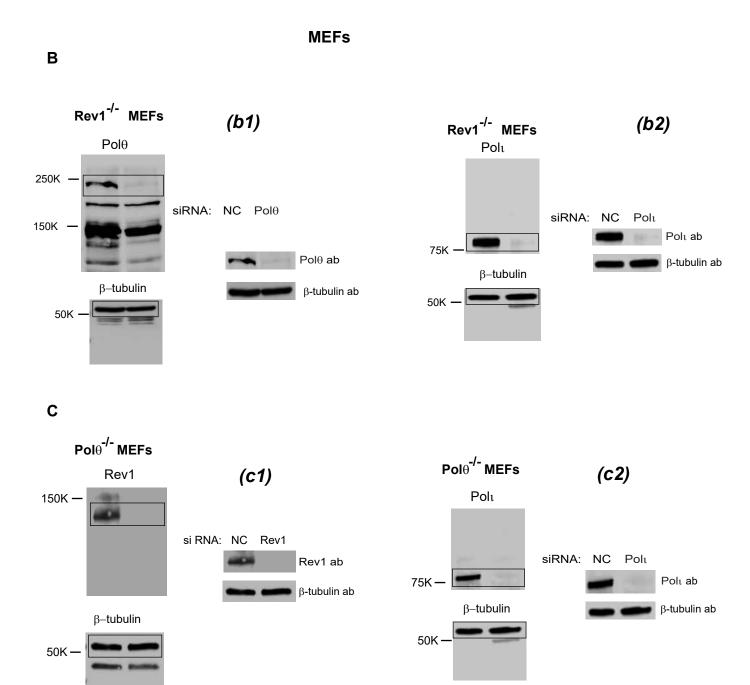


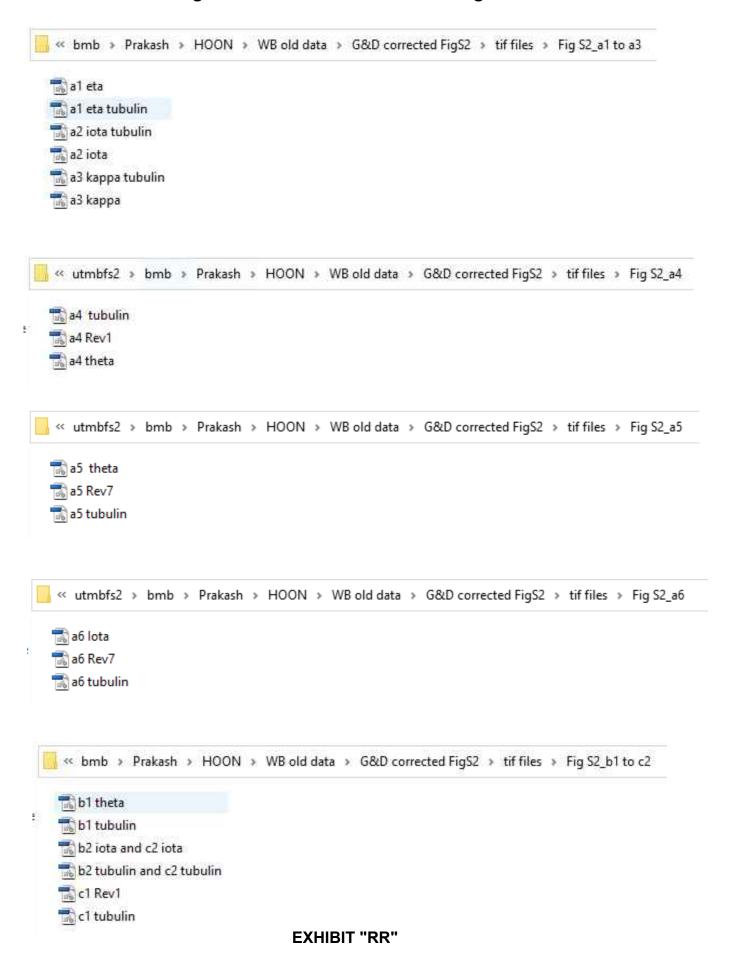
Figure S2 (parts a4 to a6)

EXHIBIT "RR"



Supplemental Figure S2 Parts B and C

Original Tif files for corrected FigS2



Prakash, Louise

From: Connell, Laureen <connell@cshl.edu>
Sent: Wednesday, October 23, 2019 2:36 PM

To: Prakash, Louise **Subject:** RE: Corrigendum

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Dear Louise,

An ai file is fine as long as the file contains an image of the entire gel with all of the lanes. We need this to see where the lanes came from and how they are being corrected.

Thank you,

Laureen

From: Prakash, Louise <loprakas@UTMB.EDU> Sent: Wednesday, October 23, 2019 3:23 PM To: Connell, Laureen <connell@cshl.edu>

Subject: RE: Corrigendum

Dear Laureen,

I assume that original data means original western blots and not just original western blots copied and pasted into adobe illustrator to show what was cropped for use in the final figure, is that correct?

Thanks, Louise

From: Connell, Laureen <<u>connell@cshl.edu</u>>
Sent: Wednesday, October 23, 2019 2:19 PM
To: Prakash, Louise <<u>loprakas@UTMB.EDU</u>>

Subject: RE: Corrigendum

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Dear Louise,

That sounds fine. If it is easier you can send the files via dropbox link.

Best,

Laureen

From: Prakash, Louise < loprakas@UTMB.EDU Sent: Wednesday, October 23, 2019 3:17 PM
To: Connell, Laureen < connell@cshl.edu>

Subject: RE: Corrigendum

Dear Laureen,

I'm putting together the materials you've requested and arranging them so that it will be easy for you to compare the original data with the final figures. I'll send them to you as soon as I've completed putting them together.

The files will be quite large so I may have to send the material in several emails.

Thank you very much.

Louise

Louise Prakash, Ph.D.
Professor, Biochemistry and Molecular Biology
Department of Biochemistry and Molecular Biology
University of Texas Medical Branch
6.104 Medical Research Building
301 University Blvd.
Galveston, TX 77555-1061

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

From: Connell, Laureen < connell@cshl.edu>
Sent: Wednesday, October 23, 2019 10:38 AM
To: Prakash, Louise < loprakas@UTMB.EDU>

Subject: Corrigendum

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Dear Dr. Prakash,

Thank you for your email. Please email me your original data for Figure S2, with an explanation for the incorrect assembly of the figures and your proposed new figures. Please also send a draft of your proposed corrigendum. If you require any assistance with the wording, please let me know. Terri and I will review everything you send and I'll get back to you as soon as I can.

Best wishes,

Laureen

Laureen Connell, Ph.D.
Senior Editor, *Genes & Development*Senior Editor, *Molecular Case Studies*1 Bungtown Rd
Cold Spring Harbor, NY 11724

From: Garite, Bibi <garite@cshl.edu> On Behalf Of Genes & Development

Sent: Tuesday, October 22, 2019 5:07 PM **To:** Connell, Laureen < connell@cshl.edu>

Subject: FW: Corrigendum

From: Prakash, Louise [mailto:loprakas@UTMB.EDU]

Sent: Tuesday, October 22, 2019 5:02 PM

To: Genes & Development < genesdev@cshl.edu>

Cc: Garite, Bibi <garite@cshl.edu>

Subject: FW: Corrigendum

Dr. Lauren Connell Senior Editor G&D

Dear Dr. Connell,

It has come to our notice that in our recent publication Yoon et al (2019) G&D 33:282-287), western blots in Supplemental Figure S2 were assembled incorrectly. We would like to replace Sections A, B, and C of Supplemental Figure S2 with a new figure for which the accuracy of each component used for compilation of the western blots has been carefully confirmed. Even though the replacement of Supplemental Figure S2 with the new figure does not change any of the information in the published figure, we think it important to publish the corrected figure as a corrigendum. We wish to stress that this change in no way affects any of the results or conclusions of this study.

Please let me know whether to send you the new figure with only Sections A, B, and C, or whether the new figure should also include Section D which shows **RC**R analyses.

Thank you very much, Louise Prakash

Louise Prakash, Ph.D.
Professor, Biochemistry and Molecular Biology
Department of Biochemistry and Molecular Biology
University of Texas Medical Branch
6.104 Medical Research Building
301 University Blvd.
Galveston, TX 77555-1061

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

From: Garite, Bibi <garite@cshl.edu> On Behalf Of Genes & Development

Sent: Tuesday, October 22, 2019 9:50 AM **To:** Prakash, Louise < loprakas@UTMB.EDU>

Subject: Corrigendum

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Louise,

I spoke with the Senior Editor, Laureen Connell, and she asked if you could send an email explaining the error in Figure S2. Then she will write back and let you know what you should do.

Many thanks,

Bibi

Bibi Garite, Administrative Assistant Genes & Development Cold Spring Harbor Laboratory Press 500 Sunnyside Boulevard Woodbury, NY 11797

Phone: 516 422 4015 Fax: 516 422 4093

Email: genesdev@cshl.edu

Prakash, Louise

From: Prakash, Louise

Sent: Thursday, October 24, 2019 1:23 PM

To: Connell, Laureen Subject: Corrigendum

Attachments: Replacement Supplemental Figure S2.ai; a1 to c2_New_Supplemental Figure S2.ai; SF2A_a1 to a3.ai;

SF2A_a4 to a6.ai; SFS2BC.ai; Corrigendum_draft.docx

Dear Laureen,

Thank you very much for your quick responses to my queries about the corrigendum.

Dr. Jung-Hoon Yoon, the first author of the paper, who had compiled the western blots for the original Supplemental Figure S2, did not keep a record of western blots used for assembling each segment of Supplemental Figure S2. Hence, we were unable to confirm that the western blots were assembled correctly. Because of our concern about the accuracy the data in Supplemental Figure S2, we asked Dr. Yoon to carry out an entirely new set of experiments so that the accuracy of each step could be unambiguously verified. We have followed this work closely, and have gone over the entire set of western blot data carefully; we are confident of its accuracy.

An image of the entire gel with all the lanes was copied and pasted into Adobe Illustrator, and the region used for the final figure is indicated by a box in the gel image. I have marked each segment in the new supplemental Figure S2 as (a1), (a2) and so on, to facilitate comparison with the corresponding ai file.

We are also sending a draft of the proposed corrigendum and the new Supplemental Figure S2 to be published with the corrigendum. The figure legend for the new Supplemental Figure S2 remains the same as was published for the original Supplemental Figure S2.

Finally, I wish to emphasize that the new data set do not alter the fact that we achieve a very high efficiency of siRNA depletion of each of the TLS Pols in HFs and MEFs and that the replacement of the original figure with this new Supplemental Figure S2 in no way affects any aspect of the published study.

Thank you very much. Louise

Louise Prakash, Ph.D.
Professor, Biochemistry and Molecular Biology
Department of Biochemistry and Molecular Biology
University of Texas Medical Branch
6.104 Medical Research Building
301 University Blvd.
Galveston, TX 77555-1061

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

Prakash, Louise

From: Connell, Laureen <connell@cshl.edu>
Sent: Thursday, October 24, 2019 2:10 PM

To: Prakash, Louise **Subject:** RE: Corrigendum

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Thank you Louise, I will review this with Terri (likely early next week) and get back to you with any questions.

Best,

Laureen

From: Prakash, Louise <loprakas@UTMB.EDU> Sent: Thursday, October 24, 2019 2:23 PM To: Connell, Laureen <connell@cshl.edu>

Subject: Corrigendum

Dear Laureen,

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Thank you very much.

Louise

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 436 of 514

Louise Prakash, Ph.D.
Professor, Biochemistry and Molecular Biology
Department of Biochemistry and Molecular Biology
University of Texas Medical Branch
6.104 Medical Research Building
301 University Blvd.
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Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

Prakash, Louise

From: Connell, Laureen <connell@cshl.edu>
Sent: Thursday, November 7, 2019 3:05 PM

To: Prakash, Louise **Subject:** RE: Corrigendum

Follow Up Flag: Follow up Flag Status: Flagged

Categories: SAVE-IMPORTANT, follow up

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Dear Louise,

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Best,

Laureen

----Original Message-----

From: Prakash, Louise <loprakas@UTMB.EDU> Sent: Thursday, October 31, 2019 7:01 PM To: Connell, Laureen <connell@cshl.edu>

Subject: RE: Corrigendum

Thank you.

----Original Message-----

From: Connell, Laureen <connell@cshl.edu> Sent: Thursday, October 31, 2019 4:53 PM To: Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Corrigendum

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I apologize, I will finalize this tomorrow with Terri.

From: Prakash, Louise [loprakas@UTMB.EDU] Sent: Thursday, October 31, 2019 5:36 PM

To: Connell, Laureen Subject: RE: Corrigendum

Dear Laureen,

I'm sorry to bother you but I was wondering if you have some idea of when I might hear from you about the corrigendum.

Thank you very much, Louise

Louise Prakash, Ph.D.

Professor, Biochemistry and Molecular Biology Department of Biochemistry and Molecular Biology University of Texas Medical Branch 6.104 Medical Research Building 301 University Blvd. Galveston, TX 77555-1061

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e-mail: loprakas@utmb.edu<mailto:loprakas@utmb.edu>

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Telephone: 409-747-8601

e-mail: loprakas@utmb.edu<mailto:loprakas@utmb.edu>

Prakash, Louise

From: Prakash, Louise

Sent: Monday, November 11, 2019 1:54 PM

To: Connell, Laureen **Subject:** RE: Corrigendum

Attachments: Revised_Corrigendum.docx

Dear Laureen,

In the revised corrigendum (attached), we have included the statements you suggested. Please let me know if it is satisfactory.

Many thanks for your help and suggestions.

Louise

-----Original Message-----

From: Connell, Laureen <connell@cshl.edu> Sent: Thursday, November 7, 2019 3:05 PM To: Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Corrigendum

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Dear Louise,

Thank you for submitting all of the items I requested for your Corrigendum. We have now had a chance to review everything you submitted, and we don't see any issues with replacing the figure. However, I would like to request that you revise the Corrigendum text to include more details about your concerns with the original figure (i.e, your concerns about the accuracy of the data) and what you are presenting in the new Fig S2 (a new set of verified experiments). Once I have the revised text from you I can publish the Corrigendum and replace Figure S2 in the next few days.

Best,

Laureen

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From: Prakash, Louise <loprakas@UTMB.EDU> Sent: Thursday, October 31, 2019 7:01 PM To: Connell, Laureen <connell@cshl.edu>

Subject: RE: Corrigendum

Thank you.

----Original Message-----

From: Connell, Laureen <connell@cshl.edu> Sent: Thursday, October 31, 2019 4:53 PM To: Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Corrigendum

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From: Prakash, Louise [loprakas@UTMB.EDU] Sent: Thursday, October 31, 2019 5:36 PM

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Louise Prakash, Ph.D.

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Telephone: 409-747-8601

e-mail: loprakas@utmb.edu<mailto:loprakas@utmb.edu>

From: Connell, Laureen <connell@cshl.edu> Sent: Thursday, October 24, 2019 2:10 PM To: Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Corrigendum

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Thank you Louise, I will review this with Terri (likely early rend getelk)ck to you with any questions.

Best,

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 442 of 514

Laureen

From: Prakash, Louise <loprakas@UTMB.EDU<mailto:loprakas@UTMB.EDU>>

Sent: Thursday, October 24, 2019 2:23 PM

To: Connell, Laureen <connell@cshl.edu<mailto:connell@cshl.edu>>

Subject: Corrigendum

Dear Laureen,

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Thank you very much.

Louise

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Telephone: 409-747-8601

e-mail: loprakas@utmb.edu<mailto:loprakas@utmb.edu>

Prakash, Louise

From: Prakash, Louise

Sent: Friday, November 15, 2019 2:09 PM

To: Connell, Laureen Subject: RE: Corrigendum

Attachments: Complete_PDF_of_Supplemental_Material.pdf

Follow Up Flag: Follow up Flag Status: Flagged

Dear Laureen,

I've attached a complete PDF of the Supplemental material with the new Supplemental Figure S2. Thanks.

Louise

Louise Prakash, Ph.D.

Professor, Biochemistry and Molecular Biology Department of Biochemistry and Molecular Biology University of Texas Medical Branch
6.104 Medical Research Building
301 University Blvd.
Galveston, TX 77555-1061

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu

----Original Message-----

From: Connell, Laureen <connell@cshl.edu> Sent: Friday, November 15, 2019 9:12 AM To: Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Corrigendum

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Louise,

I apologize for the misunderstanding, but aswrote below, I do need a complete PDF of all your supplemental material with the revised Fig S2. Your published paper has one PDF of supplemental material (see https://nam03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fgenesdev.cshlp.org%2Fcontent%2F33%2F5-6%2F282%2Fsuppl%2FDC1&data=02%7C01%7Cloprakas%40UTMB.EDU%7C5a89788449b74a24c30508d769de3e44%7C7bef256d85db4526a72d31aea2546852%7C0%7C0%7C637094275571646856&sdata=%2B2g5BjnUex2NcgKIIZAb%2FKi8sP%2F5yhB1%2BSPDtZlw018%3D&reserved=0) and therefore I cannot just post a new Fig S2. I aviil need new PDF to replace the one that is currently posted.

Best,

Laureen

Laureen Connell, Ph.D.
Senior Editor, Genes & Development
Senior Editor, Molecular Case Studies
1 Bungtown Rd
Cold Spring Harbor, NY 11724

From: Prakash, Louise [loprakas@UTMB.EDU] Sent: Thursday, November 14, 2019 6:46 PM

To: Connell, Laureen Subject: RE: Corrigendum

Dear Lauren,

Thank you very much for your email. I am sending you the new Supplemental FigS2 that includes panel D. There is no change in panel D; it remains the same as in the original published figure. Similar to the original figure, this new figure is labeled as Supplemental_Fig_S2.pdf.

Thanks again for all your help.

Louise

----Original Message-----

From: Connell, Laureen <connell@cshl.edu> Sent: Thursday, November 14, 2019 3:41 PM To: Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Corrigendum

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Louise,

Sorry, I read that incorrectly. I just need the updated supplemental material PDF, with the figure labelled as Supplemental Figure S2. I can't use the individual figure file since you have a complete PDF online now.

Laureen

From: Prakash, Louise [loprakas@UTMB.EDU] Sent: Thursday, November 14, 2019 4:30 PM

To: Connell, Laureen Subject: RE: Corrigendum

Hi Lauren,

I guess I didn't clarify but we are not omitting panel D from the figure. We want it kept in. I will send you the new figure
that has parts A, B, C, and D. Do you want ai and pdf files, and what should I call the new figure? New Supplemental
Figure S2 or replacement Supplemental Figure S2 or Supplemental Figure S2?

rigure 32 of replacement supplemental rigure 32 of supplemental rigure 32:
Thanks
Louise
Original Message From: Connell, Laureen <connell@cshl.edu> Sent: Thursday, November 14, 2019 3:28 PM To: Prakash, Louise <loprakas@utmb.edu> Subject: RE: Corrigendum</loprakas@utmb.edu></connell@cshl.edu>
WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.
Hi Louise,
If you are omitting panel D from Fig 2S, then I will need the following:
1. An updated word doc of the Corrigendum text explaining that panel D was removed and why it has been removed (was it part of the original figures and accuracy could not be confirmed?).
2. A complete PDF with the updated Fig 2S and revised legend.
Thank you,
Laureen
From: Prakash, Louise [loprakas@UTMB.EDU] Sent: Thursday, November 14, 2019 4:22 PM To: Connell, Laureen Subject: RE: Corrigendum
Dear Lauren,
Sorry for the omission but we do want to include panel D in the Supplementary Figure. I'll send you a new Supplemental Figure shortly that includes panel D. I can send but the illustrator file and the pdf file. Should the replacement figure be labeled just as Supplemental Figure S2, or should it say Replacement Supplemental Figure S2 Replacement Supplemental Figure S2 Replacement figure.
Again, I apologize for any inconvenience.

3

Thank you very much,

Louise

----Original Message-----

From: Connell, Laureen <connell@cshl.edu> Sent: Thursday, November 14, 2019 2:49 PM To: Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Corrigendum

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Dear Louise,

Thank you for sending the revised text, which looks fine now. In checking over the files again, I see that you did not include panel D in the new figure. Did you mean to omit this, or were there no changes to Fig 2SD? In addition, I see that your supplemental material is a complete PDF on our website. Could you please send me a revised PDF to replace what you have now? I cannot replace the individual figure withing the PDF.

Best,

Laureen

From: Prakash, Louise [loprakas@UTMB.EDU] Sent: Monday, November 11, 2019 2:53 PM

To: Connell, Laureen Subject: RE: Corrigendum

Dear Laureen,

In the revised corrigendum (attached), we have included the statements you suggested. Please let me know if it is satisfactory.

Many thanks for your help and suggestions.

Louise

----Original Message-----

From: Connell, Laureen <connell@cshl.edu> Sent: Thursday, November 7, 2019 3:05 PM To: Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Corrigendum

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Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 447 of 514

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301 University Blvd. Galveston, TX 77555-1061

Telephone: 409-747-8601

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Louise Prakash, Ph.D.

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e-mail: loprakas@utmb.edu<mailto:loprakas@utmb.edu>

Prakash, Louise

From: Prakash, Louise

Sent: Thursday, October 24, 2019 1:23 PM

To: Connell, Laureen Subject: Corrigendum

Attachments: Replacement Supplemental Figure S2.ai; a1 to c2_New_Supplemental Figure S2.ai; SF2A_a1 to a3.ai;

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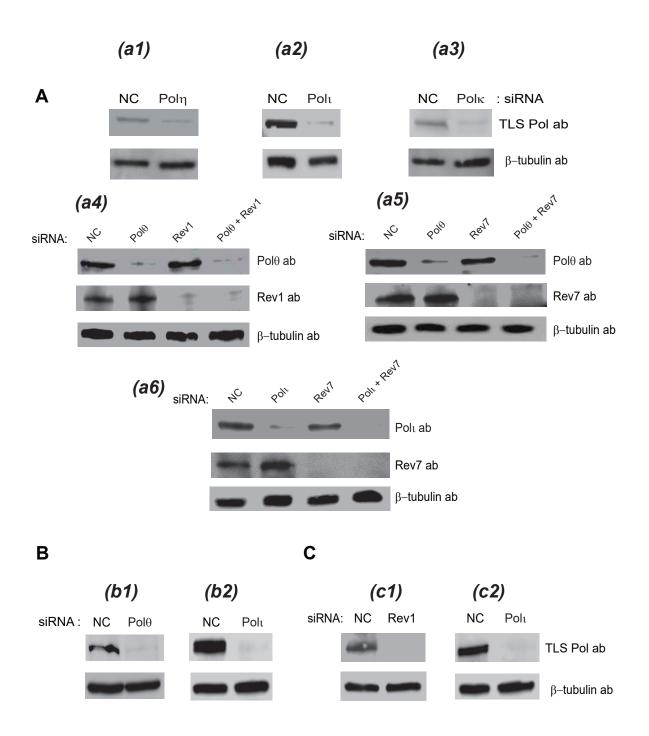
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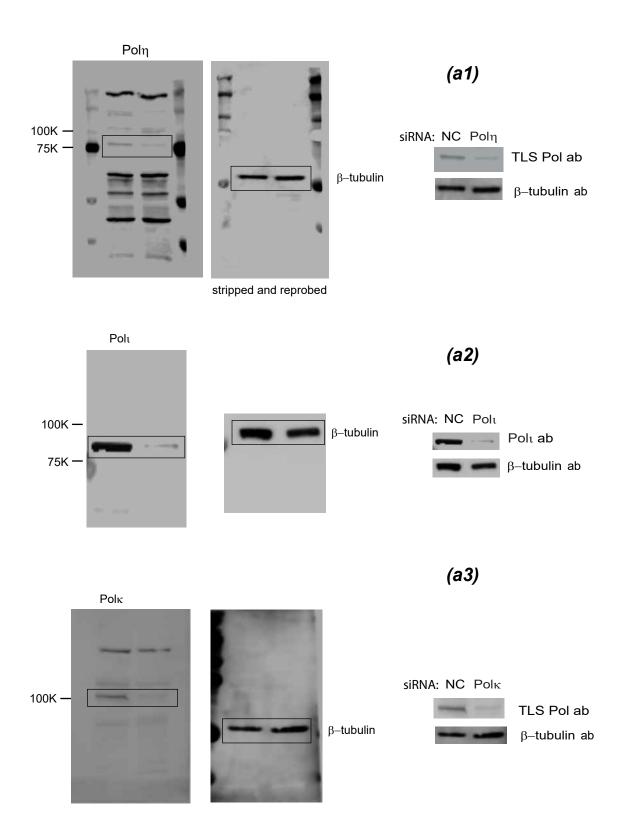
Louise Prakash, Ph.D.
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301 University Blvd.
Galveston, TX 77555-1061

Telephone: 409-747-8601 e-mail: loprakas@utmb.edu



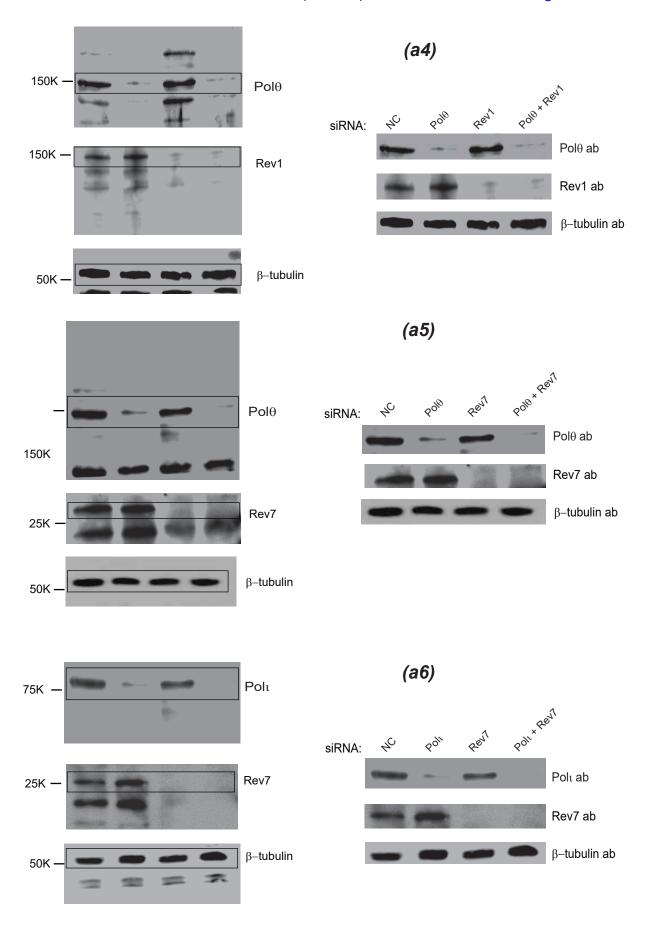
New Supplemental Figure S2 (marked for easy linking to ai files)

Normal HFs (GM637)



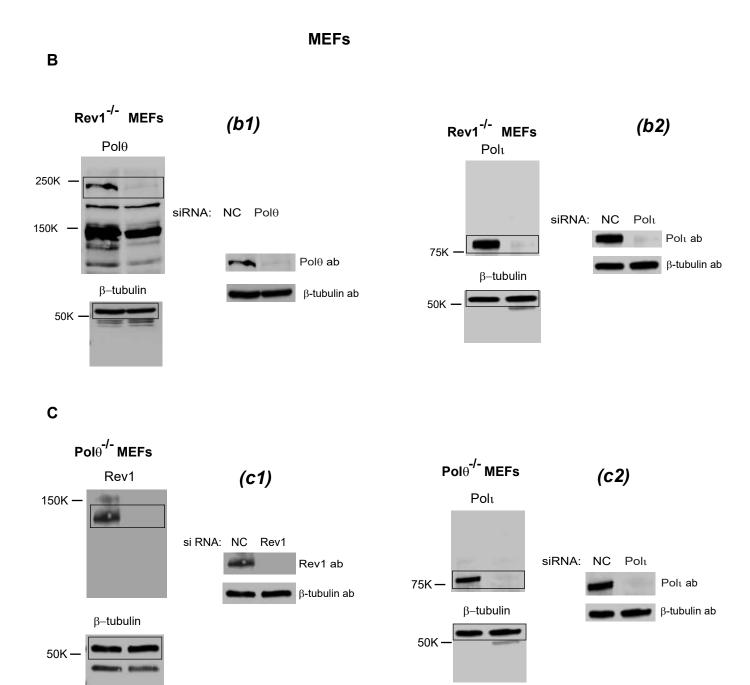
Supplemental Figure S2 (parts a1 to a3)

EXHIBIT "RR"



Supplemental Figure S2 (parts a4 to a6)

EXHIBIT "RR"



Supplemental Figure S2 Parts B and C

Case 4:22-cv-0408 EXHIBITITIE FIRE Communication and e 455 of 514 Notes from Complainant

From:
To: Garg, Nisha
Subject: Fabrication

Date: Tuesday, April 30, 2019 5:46:13 PM

Hi Dr. Garg,

I am leaving UTMB by May 10th 2019, and I need to report some misconduct of my colleague (Dr. Jung Hoon Yoon) in same lab I'm working in. Actually, I have decided my resignation because of the fraud. About two month ago, I noticed that Dr. Yoon and my PIs published a paper, and found out Dr. Yoon fabricated some data in the supplemental figures using my western blot data. I do not know it affects the conclusion of the paper, but I just thought that it just closed the line.

Because He is a quite influential person for making a direction for our research, I lost my confidence on our research anymore. That's the reason I made my mind to leave.

My PIs (Dr Satya Prakash and Louise Prakash) are totally relying on him, and I believed that they do not know the fraud. They just did not check the raw data when they submitted the paper. I've never told them about what I found. I just don't want to be involved in very awkward situation until I leave.

I have the evidence to prove his intentional fabrications in the paper. First of all, I have been only person who generated western blot data over 8 years. Dr. Yoon never did single western blot after I joined the lab. He mislabeled my western blot data for the publication.

I am willing to testify If it is needed for better ethical science.

Because, the severity of this matter, <u>please keep it confidential</u>. <u>I assume that you are not trying to contact my boss until I leave Galveston</u>. Obviously, they will identify me as the whistleblower considering detailed information which hard to be reached, but I need some time until I go back to my home country for a new job. Please let me know what I should do for resolving this. Thank you.

Sincerely yours

Biochemistry and Molecular Biology

University of Texas Medical Branch

301 University Blvd.

Galveston, TX 77555-1061





The University of Texas Medical Branch SCHOOL OF MEDICINE

Dr. Louis Prakash and Dr. Satya Prakash Department of Biochemistry and Molecular Biology UTMB Galveston

September 16, 2019

Dear Dr. L Prakash and Dr. S Prakash

I have received allegations of possible research misconduct in the form of falsification of figures in a manuscript. Specific allegation is against the first author of the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019). The complainant who wishes to remain anonymous alleged that there were discrepancies in Supplemental Figure S2:

Panel A - top left: blot for TLS Pol in NC/Poln samples is from another blot for a different protein.

Panel A - middle left: Pol ϕ data is from another blot for a different protein in different cells, Rev1 blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Poli data are from a blot for another protein.

Panel B- Western blot for Pol ι and tubulin for NC/Pol ϕ samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data

This manuscript cites support from US PHS funds, specifically NIH grants ES022948 and GM126087. As this possible falsification occurs in research funded by NIH, we are bound to conduct an inquiry to determine whether there is evidence of potential falsification to warrant and investigation.

As a part of inquiry, we may need to sequester all relevant digital and hard copy research records related to the questioned work so that they can be reviewed by the Scientific Integrity Committee at the UTMB.

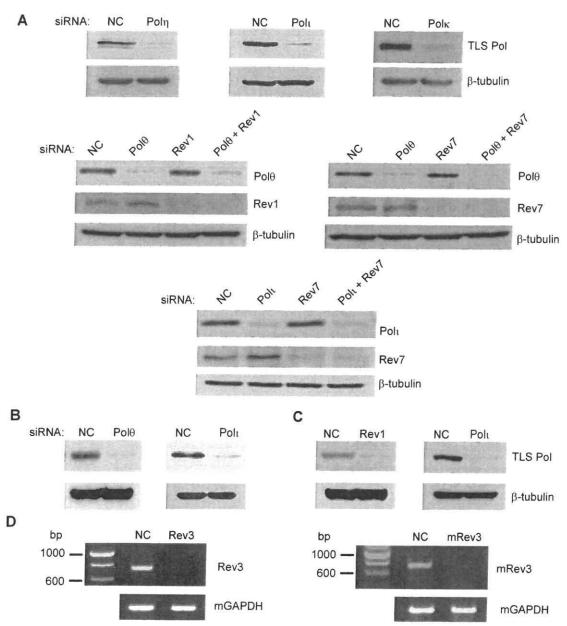
Sincerely

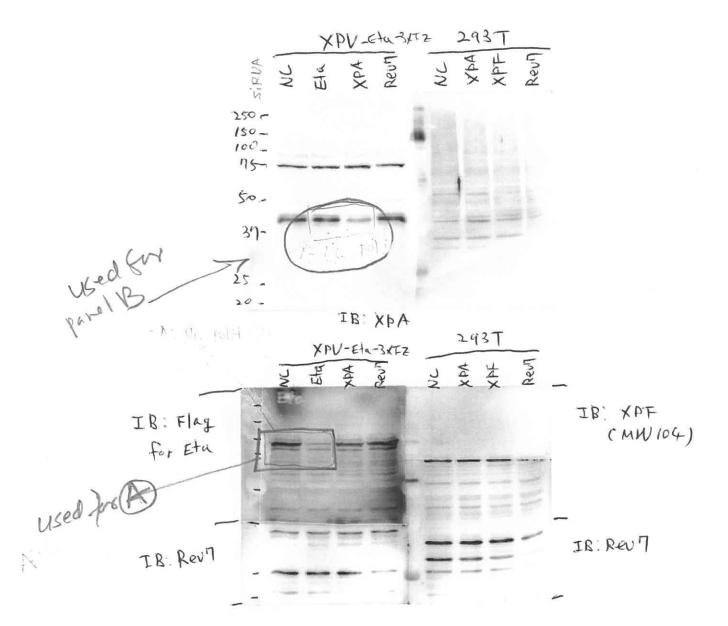
Nisha J Garg (PHD MBA) Scientific Integrity Officer

UTMB Galveston

Case 4:22-cv-04089 Doo

Supplemental_Fig_S2.pdf





Page Z

WB6

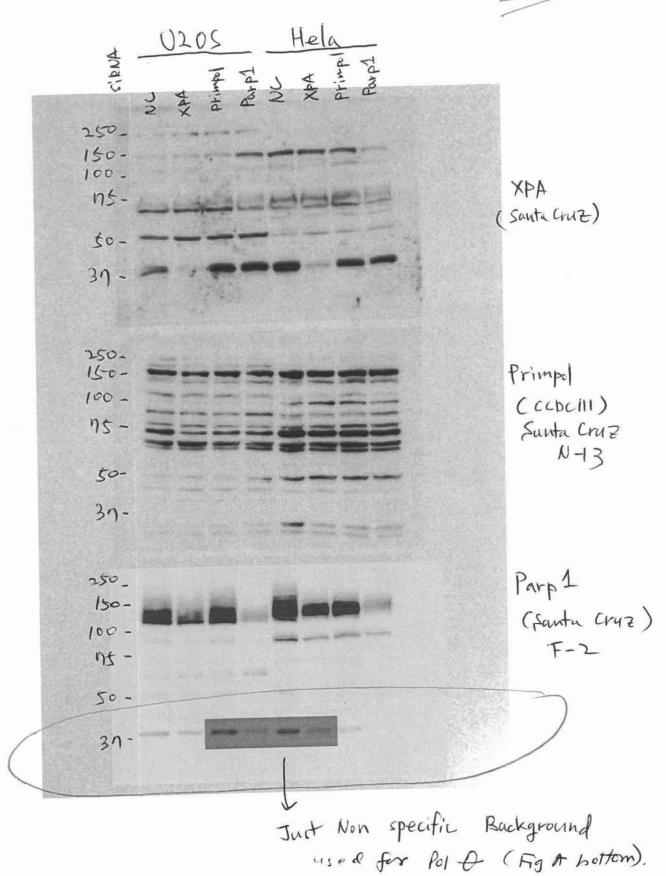
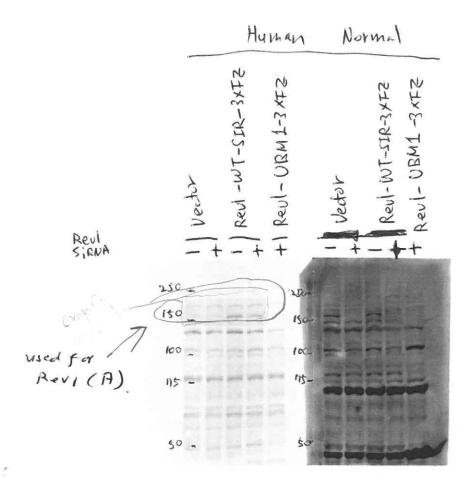


EXHIBIT "RR"

page 3



IB: Flag

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Normal 250 150 SCC1 100 75 750 Wapal (Usodfor Rev 7) 1001 250 -A2204 ← 100 -75WB For 4:28-dv-04089 Document 1 Filed on 11/23/22 in TXSD Page 463 of 514

10-13-14

Sume to Membranes on 10-10-14 (Jabelled but rebloted for x-tubulin page 2

Brubulin

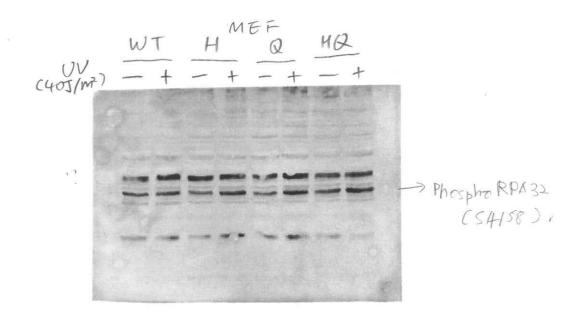
From different

cell live

used for A

(B-Tub)

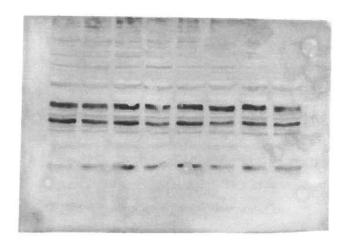
page 5

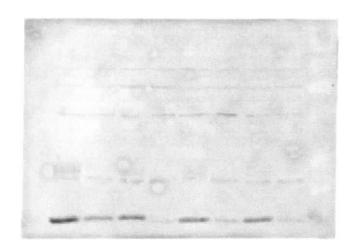




Page 7

WBn

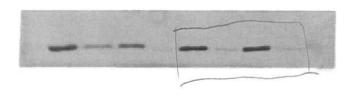




Page 8

WB7 Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 466 of 514

The mirror image

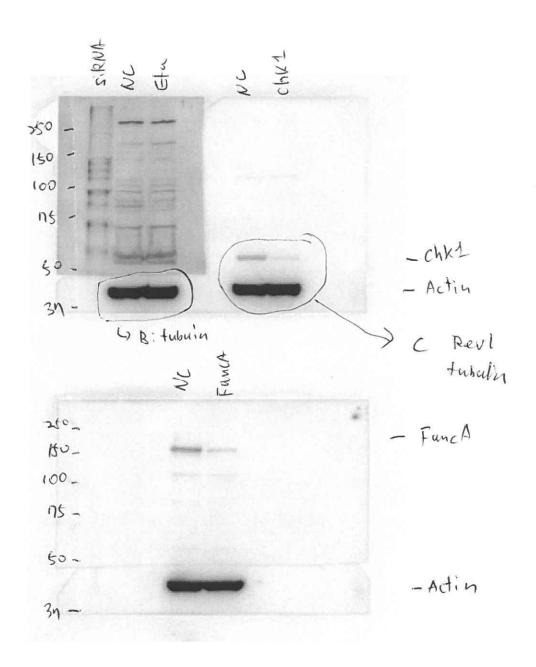


Mirror image

WBT

Pageg

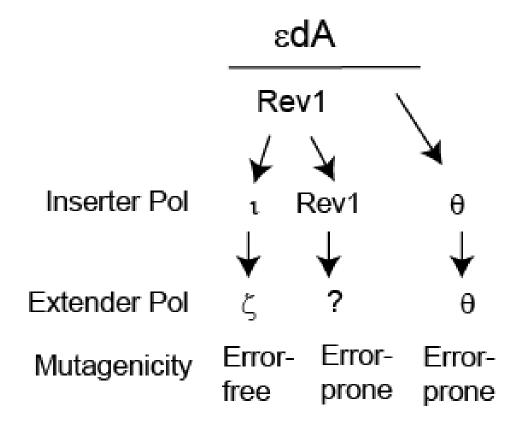
MCFIOA



Page 10

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD. Page 468 of 514 EXHIBIT D - Presentation by Dr. Yoon at SIO interview on May 19, 2022

TLS pathways for replicating through etheno-dA in human cells



Supplemental Table S1

Effects of siRNA knockdown of TLS polymerases on the replicative bypass of the εdA lesion carried on the leading strand template in wild type, Rev1-/-, or Polθ-/- MEFs

MEFs	siRNA	Number of Kan* colonies	Number of blue colonies among Kan [†]	TLS (%)	
WT	NC	422	94	22.3	
	NC	350	28	8.0	
D2424	Poli	308	26	8.4	
Rev1-	Rev3	296	24	8.1	
	Polθ	411	4	1.0	
Pole-/-	NC	387	44	11.4	
	Poli	432	15	3.5	
	Rev3	408	14	3.4	
	Rev1	367	4	1.1	

Supplemental Table S3

Effects of catalytically active (WT) Rev1 or catalytically inactive D570A E571A mutant Rev1 on TLS opposite εdA carried on the leading strand template in Rev1-MEFs

Vector expressing	Number of Kan ⁺ colonies	Number of blue colonies among <i>Kan</i> ⁺	TLS (%)	TLS pathway that remains active
_	458	38	8.3	Polθ
WT Rev1	364	70	19.2	Polι/Polζ, Rev1 Pol, Polθ
Catalytic mutant Rev1	306	48	15.7	ΡοΙι/ΡοΙζ, ΡοΙθ

Supplemental Table S5

Effects of catalytically active (WT) or catalytically inactive D2540A E2541A mutant (1708-2590) Polθ on TLS opposite εdA carried on the leading strand template in Polθ-/- MEFs

Vector expressing	Number of <i>Kan</i> ⁺ colonies	Number of blue colonies among <i>Kan</i> ⁺	TLS (%)	TLS pathways that remain active
_	381	42	11.0	Pol ₁ /Polζ, Rev1 Pol
WT Polθ	332	73	22.0	Pol ₁ /Polζ, Rev1 Pol, Polθ
Catalytic mutant Polθ	295	31	10.5	PolιPolζ, Rev1 Pol

Supplemental Table S6

Effect of wild type Polθ, catalytically active (WT) Rev1, or catalytically inactive D570A E571A mutant Rev1 on mutation frequencies and nucleotides inserted opposite εdA carried on the leading strand DNA template in wild type, Rev1^{-/-}, or Polθ^{-/-} MEFs

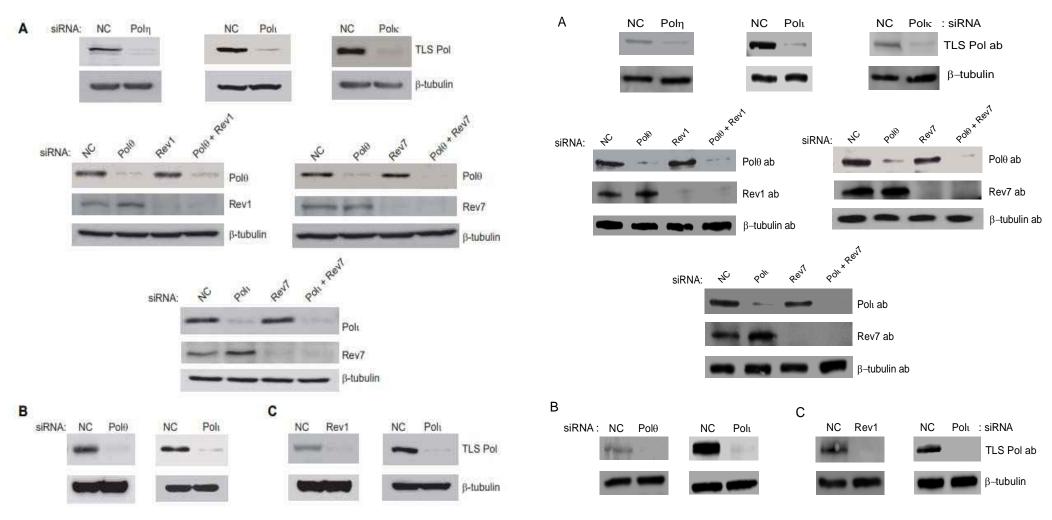
MEFs	Vector expressing, siRNAs	No. of <i>Kan</i> + blue colonies sequenced	Nucleotide inserted				Mutation frequency (%)	Error-prone TLS pathway that remains
			Α	G	С	Т	(,,,	active
WT	None	96 (12) ^a	3	0	9	84	12.5	Rev1,Polθ
Pol⊕	Vector control	96 (9)	1	0	8	87	9.4	Rev1
Rev1 ^{-/-}	Vector control	96 (8)	4	0	4	88	8.3	Polθ
Rev1 ^{-/-} (mPolθ siRNA) ^b	Flag-Mutant - Rev1	90 (0)	0	0	0	90	0	none

^aNumber of colonies where TLS occurred by insertion of a nucleotide other than T are shown in parentheses.

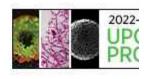
^bRev1^{-/-}MEFs were treated with mPolθ siRNA. In these MEFs carrying Flag-mutant Rev1, only the Pol₁/Polζ dependent error-free pathway remains active.



Corrected Figure S2







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See original article: Yoon et al. 33 (5-6): 282.

Corrigendum: DNA polymerase θ accomplishes translesion synthesis opposite 1,N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash and Satya Prakash

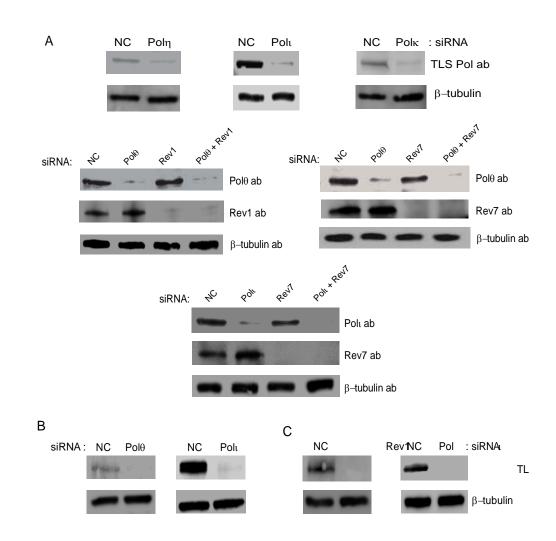
Genes & Development 33: 282-287 (2019)

In Supplemental Figure S2 in the above article, we have been unable to confirm that the Western blots in panels A-C were assembled correctly. Because of our concerns about the accuracy of the data in the Western blots, we are presenting a new set of verified experiments in the new Supplemental Figure S2, which can be found in the Revised Supplemental Material online. This change in no way affects any of the results or conclusions of this study. The authors apologize for this error.

doi: 10.1101/gad.334946.119

Published by Cold Spring Harbor Laboratory Press

Corrected Figure S2





Implications of inhibition of Rev1 interaction with Y family DNA polymerases for cisplatin chemotherapy

Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satva Prakash

Department of Biochemistry and Molecular Biology, University of Texas Medical Branch, Galveston, Texas 77555, USA

Chemotherapy with cisplatin becomes limiting due to toxicity and secondary malignancies. In principle, therapeutics could be improved by targeting translesion synthesis (TLS) polymerases (Pols) that promote replication through intrastrand cross-links, the major cisplatin-induced DNA adduct. However, to specifically target malignancies with minimal adverse effects on normal cells, a good understanding of TLS mechanisms in normal versus cancer cells is paramount. We show that in normal cells, TLS through cisplatin intrastrand cross-links is promoted by Poln- or Pola-dependent pathways, both of which require Rev1 as a scaffolding component. In contrast, cancer cells require Rev1-Polζ. Our findings that a recently identified Rev1 inhibitor, JH-RE-06, purported to specifically disrupt Rev1 interaction with Polζ to block TLS through cisplatin adducts in cancer cells, abrogates Rev1's ability to function with Y family Pols as well, implying that by inactivating Rev1-dependent TLS in normal cells, this inhibitor will exacerbate the toxicity and tumorigenicity of chemotherapeutics with cisplatin.

[Keywords: DNA repair, nucleotide excision repair; translesion synthesis; Y family DNA polymerases, cisplatin intrastrand cross-links; Rev1]

Supplemental material is available for this article.

Received May 11, 2021, revised version accepted July 15, 2021.

----Original Message-----

From: Oddo, Dorothy <doddo@cshl.edu> Sent: Saturday, July 17, 2021 7:09 PM

To: Prakash, Satya <saprakas@UTMB.EDU>

Subject: Publicity efforts on the Yoon-Prakash manuscript

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Prakash,

Congratulations on having your paper, "Implications of inhibition of Rev1 interaction with Y-family DNA polymerases for cisplatin chemotherapy," by Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satya Prakash, accepted for publication in the September 2021 issue of Genes & Development.

We wanted to get in touch with you regarding potential publicity efforts for your G&D manuscript. We are optimistic that general media outlets &/or other scientific journals – such as Science, Nature, Nature Reviews - might be interested in covering this. To facilitate this, we would like to get in touch with the media affairs contact at your institution to see if/what publicity efforts they have planned for your upcoming paper.

If you could please send me the appropriate contact name and e-mail address for someone at your institution I will look into this.

Thanks very much for all of your help,

Dorothy Oddo

Editorial Office

Genes & Development

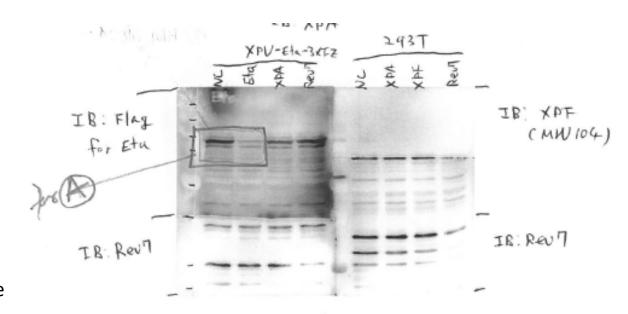
Response for Panel A. a.

From originally published Fig. S2



What was used for panel A.a. is Pol eta but there is more space in the 2 bands in evidence file

From what was sent in evidence file



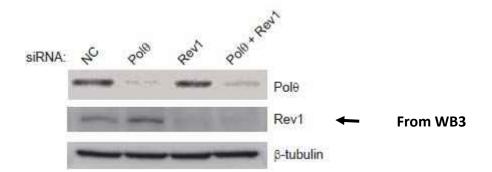
Response for Panel A. b.

WB3

10-3-13

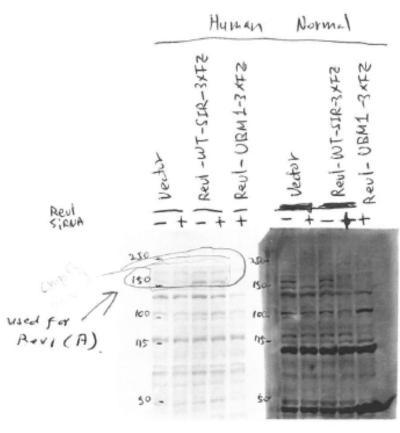
WB3

From originally published Fig. S2



It's hard to tell because bands in evidence file do not show up well and they would have to be the mirror image of what was published; and the Rev1 band in lane 2 is curved more than in the evidence file

From what was sent in evidence file



IB: Flag

Santa Cruz Sc-48806

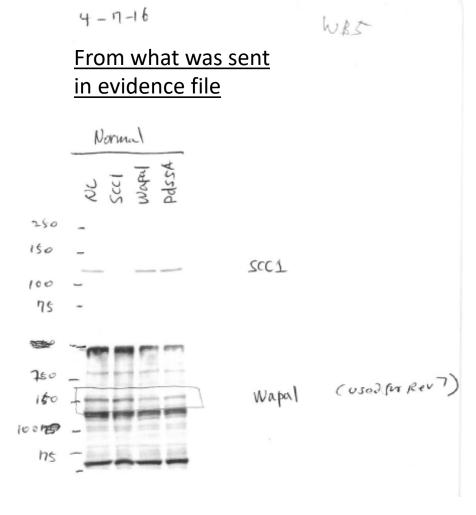
EXHIBIT "RR"

Case A:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 479 of 514 Response for Panel A.C/A.e.

- c. The Rev7 images appear to be highly similar to ~150kDa bands for a different protein that are labeled differently. Tubulin data appear to be from a different experiment.
- d. β-tubulin appear to be from a different cell line and experiment from 10-13-14
- e. Lane labeled siRNA, Rev -7 highly similar to ~150kDa bands from WB 5 (WAPAL).

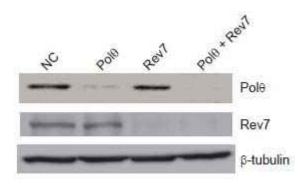
From originally published Fig. S2 Pole Rev7 From WB5

The intensity of the 2 bands on the right in the evidence file show up fairly well but they don't in Fig. S2.



Response for Panel A. d.

From originally published Fig. S2



Tubulin bands are supposed to have come from 10-13-14. Since the evidence file is supposed be stripped and reblotted blot of 10-10-14 (WB4), it's very hard to tell which blot was actually stripped and reprobed.

From what was sent in evidence file

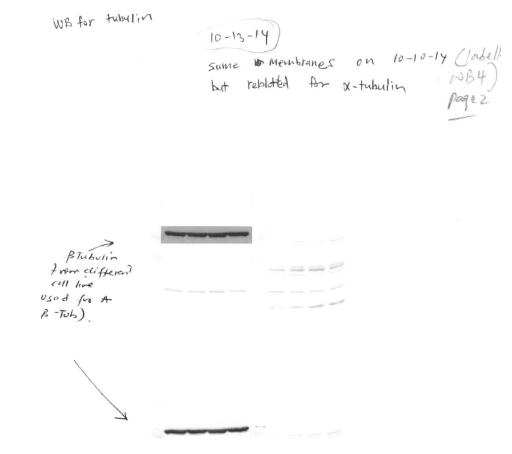
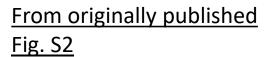
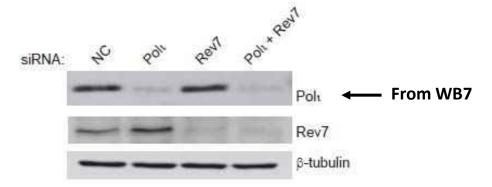


EXHIBIT "RR"

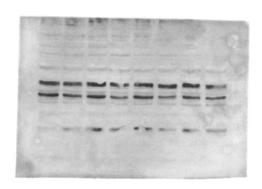
From what was sent in evidence file

WBM

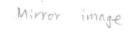




In Fig. S2, lane 3 seems to curve upward to a greater extent than in blocked portion of the evidence file. There is no labelling on the evidence file.



Mirror Image of 11-30-19





Response for Panel B.a.

WB4

From originally published <u>Fig. S2</u>

Polt NC From WB4

In Fig. S2, there is no doublet in band in NC lane but there is one in the evidence file. Also, left part of Poli band in lane 2 of Fig S2 is less intense than right portion whereas intensity of band in Evidence file is more uniform

From what was sent in evidence file

10-10-14

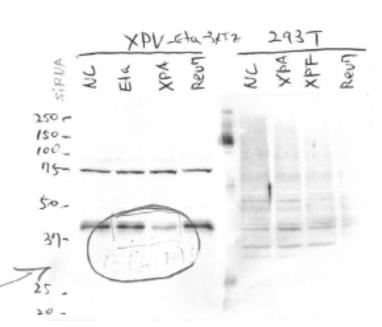
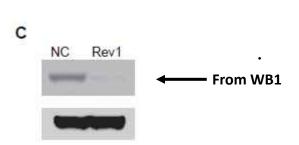


EXHIBIT "RR"

Response for Panel C.a.

WB1

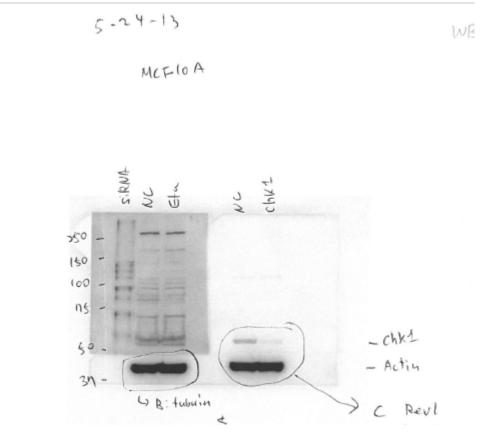
From originally published Fig. S2



In Fig. S2, lane 1, NC, shows more curvature than in evidence file. Also, in lane 2 of Fig. S2, Rev1 band is not visible and left side Rev1 band is darker than right side but in evidence file, right side is darker.

Tubulin bands do not match.

From what was sent in evidence file



Response to Scientific Integrity Committee Inquiry Report

By

Dr. Jung `Hoon Yoon October 3, 2022

Executive Summary

- 1. The Scientific Integrity Committee ("SIC") has failed to provide any factual support for their request to initiate an investigation.
- 2. Multiple statements made by the SIC in coming to its conclusion are factually incorrect.
- 3. An investigation is also not warranted because Dr. Yoon has produced all the documents in his possession to the SIO and SIC and he has been thoroughly interviewed twice; there is nothing else for an investigation to receive or learn.
- 4. To support a claim for scientific misconduct, the SIC had to show that Dr. Yoon intended to commit fraud, which it has failed to do. Indeed, upon learning of his mistake, Dr. Yoon reran the experiments to produce a new Supplemental Figure under the watchful eyes of Drs. Louise and Satya Prakash and published it in a corrigendum in Genes & Development, where Dr. Yoon owned his mistake by publicly acknowledging it to the public.
- 5. Dr. Yoon has had to deal with a number of inquiries/investigations over more than three years, all of which have violated Dr. Yoon's legal due process rights, as each failed to follow UTMB's mandated procedures and violated federal law. In particular, multiple sections of federal law 42 CFR Section 93.
- 6. An investigation is not warranted as the evidence shows that at worst, Dr. Yoon was careless putting together a figure that was not substantive to the paper's findings and conclusions.

Introduction

This reply is being provided to rebut the SIC inquiry report that requests that an investigation be initiated into an error by Dr. Jung Hoon Yoon (hereinafter, "Dr. Yoon") regarding the preparation and publication of Figure S2 as part of a paper published in Genes & Development issue of March 1, 2019. Dr. Yoon does not believe an investigation is warranted as there is nothing more to learn and nothing learned to date supports a claim of scientific misconduct. To start, Dr. Yoon has produced all of the documents and electronic files in his possession that are relevant to this matter to Dr. Niesel and the SIC. He has also been extensively interviewed by Dr. Niesel and the SIC on those documents and electronic files and the facts of his mistake. It is not clear to Dr. Yoon what exactly an investigation can learn that has not already been identified and determined by Dr. Niesel and the SIC.

Further, in coming to their conclusion that an investigation should be initiated, the SIC has made multiple conclusory and/or factual statements that the SIC fails to support with actual evidence or that are factually inaccurate. Instead, it is pretty clear that the SIC is making statements based on their opinions, not facts. This is highly problematic as the SIC has been charged with making a determination about Dr. Yoon's future employment and reputation and such a determination must be made based on actual facts. It is unreasonable and unfair for the SIC to come to a conclusion because they "think" something may be possibly true. There are no facts to support initiating an investigation and as stated, no new facts will come to light that have not already been made known to and reviewed by Dr. Niesel and the SIC.

Next, the inquiry and an investigation are to determine if Dr. Yoon committed "scientific misconduct." This is not determined based on a "mistake" standard. For scientific misconduct to be found, there must be intentional, knowingly or reckless actions of fabrication, falsification, plagiarism or other actions that materially deviate from those commonly accepted by the academic community. Here, the SIC has failed to show that Dr. Yoon's actions violated any of these factors. Dr. Yoon does not dispute that he made a mistake and that he could be found careless in not keeping adequate records of the gels he used to create the original Supplemental Figure. But nothing he did rose to the level of scientific misconduct. Particularly, nothing has been found by Dr. Niesel or the SIC to suggest his actions were intentional, knowingly undertaken or reckless. Moreover, upon learning of the error, Dr. Yoon immediately reran all the experiments, ran new western blots and produced a new Supplemental Figure under the watchful eyes of Drs. Louise and Satya Prakash that was published as a corrigendum by Genes and Development. In fact, the corrigendum admitted the mistake in writing for all of the journal's readers to see.

Further, this whole process started in September 2019 based on a complaint filed in April 2019. Since that time, Dr. Yoon has had to deal with one failed inquiry attempt after another. Indeed, the original Scientific Integrity Officer ("SIO"), Dr. Nisha Garg violated Dr. Yoon's due process rights, by failing to follow UTMB's mandated procedures and federal law. Particularly multiple violations by Dr. Garg and others at UTMB and in the UT system of sections of 42 CFR Part 93 through not one, not two but three failed inquiry attempts. In fact, Dr. Garg's first attempt, was rubber stamped by UTMB's General Counsel, at the time Carolee King, and former President Raimer, in violation of UTMB's mandated procedures and federal law. Additionally, Dr. Yoon has been informed that the NIH Office of Research Integrity is currently investigating the actions of Dr. Garg related to her violation of federal law in her investigation of Dr. Yoon.

Moreover, even this current attempt at an inquiry that has been conducted under the guidance of Dr. Niesel has also violated Dr. Yoon's due process rights. Under both UTMB's mandated procedures and federal law, an inquiry is to take place sixty (60) days between its start and the issuance of the SIC inquiry report. Dr. Yoon was notified on February 26, 2022 by Dr. Niesel that an inquiry was being initiated. The SIC report was not provided to Dr. Yoon until August 23, 2022, almost 180 days later. This is not even taking into account the fact that Daniel Sharphorn, the University of Texas System General Counsel informed Dr. Yoon on October 15, 2021, about a year ago, that this new inquiry was to be launched following the firing of Dr. Garg as SIO. So, for over three years Dr. Yoon has been dragged through one illegal inquiry after another for what clearly amounts to an honest mistake.

In the end, Dr. Yoon has suffered greatly for over three (3) years since the first of several attempts to conduct a procedurally and legally correct inquiry was initiated, including one whose illegal investigation report presented in January 2020 stated that Dr. Yoon should be fired. His physical health has suffered greatly and the process has also seriously affected his mental health. There is no reason to continue this process. An investigation should not be initiated. The SIC recommendation should be summarily rejected. With regard to punishment for Dr. Yoon's mistake and carelessness, the emotional and physical toll he has suffered during the last over three (3) years is more than sufficient punishment. Indeed, since January 2020, Dr. Yoon has had to wonder if he would be allowed to continue conducting research in the Prakash lab at UTMB, where he has made significant contributions, after the first procedurally and illegal inquiry/investigation told him he should be fired. No other punishment is warranted. Dr. Yoon respectfully requests that the SIC request to initiate an investigation should be rejected and this matter ended summarily.

Failure to Support a Claim of Scientific Misconduct

The first issue that needs to be dealt with is what is "scientific misconduct." What it is not is a mistake or carelessness. More particularly, as defined by the federal code under 42 CFR §93.104, a finding of scientific misconduct requires that:

- (a) "There be a significant departure from accepted practices of the relevant research community; and
- (b) The misconduct be committed intentionally, knowingly, or recklessly; and
- (c) The allegation be proven by a preponderance of the evidence." (emphasis added)

This definition of scientific misconduct is reiterated by the UTMB Policy and Procedure Manual on Integrity in Research ("PPMIR"), where Misconduct/Fraud in research is defined as:

"fabrication, falsification, plagiarism, or other practices that materially deviate from those that are commonly accepted within the academic community for proposing, conducting, or reporting research. It does not include honest errors or honest differences in interpretations or judgments of data." (emphasis added)

As stated by the UTMB PPMIR, honest errors are not misconduct or fraud. Real scientific misconduct or fraud requires an intent to commit the act. To do the bad thing. This is more than making an honest mistake or being careless. Particularly, one as stated by Dr. Niesel during his interview with Dr. Yoon, was a mistake he owned up to when the corrigendum with Genes & Development was filed. As is detailed below, the SIC has failed to show that Dr. Yoon intended to commit misconduct or fraud and

the SIC has failed to meet the standard required to support a claim of scientific misconduct under federal law or the UTMB PPMIR.

The SIC made several statements in its August 23, 2022 memorandum that are factually incorrect. More particularly, the SIC has made claims about statements made by Dr. Yoon during his interview that are not correct. For instance, the SIC states that

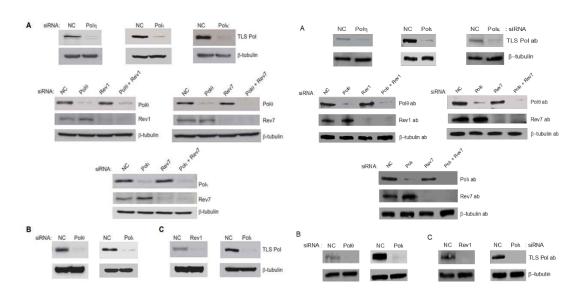
"During that interview, Dr. Yoon acknowledged that the published data was incorrect and was mistakenly included in the manuscript." (3. Background p. 1).

"The respondent stated that he was under high pressure and in a hurry at the time and the incorrect data being utilized was an honest mistake." (IX. Evidence Supporting the SIC's Recommendation to Conduct an Investigation p. 3).

Dr. Yoon did not make the statement that the data was incorrect either during his interview with Dr. Niesel on May 19, 2022 or his interview with the SIC on August 8, 2022. There is no evidence that in putting together the original published Supplemental Figure that Dr. Yoon did not believe he was creating an accurate figure for publication with the correct data. The SIC has failed to produce any evidence to show that the data used to create the original Supplemental Figure was incorrect. Indeed, what is noteworthy is that the Supplemental Figure in the corrigendum appears essentially the same as the original Supplemental Figure.

Original Supplemental Figure 2

Corrigendum Supplemental Figure 2



The Evidence Cited by the SIC Does Not Support a Claim of Scientific Misconduct or Fraud

As evidence supporting a request to initiate an investigation into Dr. Yoon, the SIC states that there were:

"issues with the labeling of images and mismatching of the data for the Figure."

"a lack of details as to the specifics of how the experiment was conducted."

Issues with the respondent being "under high pressure and in a hurry at the time the incorrect data being utilized was an honest mistake."

"a lack of rigor in the approach to assembling this data for this supplementary Figure."

There is nothing in what the SIC claims that supports the initiation of an investigation that would lead a reasonable person to believe that Dr. Yoon undertook actions with the intent to commit scientific misconduct or fraud. Was Dr. Yoon careless in not keeping accurate records of which gels he used to create the original published Supplemental Figure – Yes. He has admitted that. He stated to both Dr. Niesel and the SIC that he was put under a lot of pressure to prepare the original published Supplemental Figure quickly. As a result, he failed to keep adequate records that would have allowed him to go back and identify the gels from which each band set came. That is being sloppy. That is being careless. What that is not is scientific misconduct or fraud. There is nothing that the SIC has stated that even if believed true supports a claim of scientific misconduct or fraud.

And a claim that an investigation would determine if there was falsification of the original data is almost nonsensical. If Dr. Yoon had fabricated the original data, he would not have rerun the experiments to create the Supplemental Figure of the corrigendum. In fact, Drs Louise and Satya Prakash followed Dr. Yoon's work to rerun the experiments and create the data used in the corrigendum Supplemental Figure and both vouch for its accuracy. Moreover, logic says that if the data was fabricated, Dr. Yoon would not have taken the chance of redoing the experiments-because if the results of the corrigendum Supplemental Figure were different, then his guilt would be self-evident. That is not what he did and not what has happened here. He reran all the experiments, he reran all the gels and put together the Supplemental Figure that was published in the corrigendum with an acknowledgement of the mistake made. In fact, in submitting the corrigendum, Dr. Louise Prakash was absolutely clear in her disclosure to Genes & Development about what had happened, when she wrote the following to Genes & Development editor Dr. Laureen Connell that:

"Dr. Jung-Hoon Yoon, the first author of the paper, who had compiled the western blots for the original Supplemental Fig. S2, did not keep a record of western blots used for assembling each segment of Supplemental Fig. S2. Hence, we were unable to confirm that the western blots were assembled correctly. Because of our concern about the accuracy of the data in Supplemental Fig. S2, we asked Dr. Yoon to carry out an entirely new set of experiments so that the accuracy of each step could be unambiguously verified. We have followed this work closely and have gone over the entire set of western blot data carefully; we are confident of its accuracy."

In the corrigendum itself, the authors of the paper published the following statement admitting the mistake (error):

"In Supplemental Fig. S2 in the above article, we have been unable to confirm that the Western blots in panels A-C were assembled correctly. Because of our concerns about the accuracy of the data in the Western blots, we are presenting a new set of verified experiments in the new Supplemental Fig. S2, which can be found in the Revised Supplemental material online. This change in no way affects any of the results or conclusions of this study. The authors apologize for this error"

That is not what someone who commits scientific misconduct or fraud would have done. This is what someone who made a mistake would do to clean up the record. That is what happened here and as Dr. Niesel stated during his interview with Dr. Yoon, Dr. Yoon owned up to his mistake.

Complainant Made False Statements to Dr. Garg

Additionally, there are serious concerns about the veracity and honesty of the complainant Jeseong Park, who was a member of the Prakash lab. In his complaint letter dated April 30 2019, Dr. Park makes several claims that are difficult to reconcile with the truth. These include his claims that:

"I have decided my resignation because of the fraud."

"I lost my confidence on our research anymore. That's the reason I made my mind to leave."

With these statements, it is clear that the complainant Dr. Park led Dr. Nisha Garg, the first SIO who dealt with this matter, and the first to violate the UTMB procedures and federal law, to believe that he had to leave the Prakash's lab due to the actions of Dr. Yoon that he allegedly discovered. He failed to notify Dr. Garg that he was filing his complaint, not upon review of the paper but only after he learned that he was not included as an author of the Genes & Development paper and that he was the third author of a Cell paper that had recently been published, instead of second author that he believed he deserved. Dr. Park blamed Dr. Yoon for these alleged slights as Dr. Park believed that Dr. Yoon did not fight for him to get the authorship Dr. Park believed he deserved. This animosity toward Dr. Yoon festered and manifested in the complaint filed against Dr. Yoon. The irony is that the majority of the gel bands alleged by Dr. Park in his complaint to constitute the ones used by Dr. Yoon in the original Supplemental Figure were in fact not used in that Figure.

Moreover, Dr. Park failed to state that he had been looking for a job for a while prior to filing the complaint with Dr. Garg. Indeed, he had accepted one on April 19, 2019, at InnoPharmamarScreen, almost two weeks *before* filing the complaint. In essence, Dr. Park had decided to leave to go back to South Korea for his own personal professional benefit, not because of some alleged issue with Dr. Yoon related to an alleged fraud. Dr. Park lied to Dr. Garg. Thus, it is not surprising that his claims about the gel bands used were also false, a fraud perpetrated by Dr. Park.

Additional Comments

What appears to have been lost over the last over three (3) years of one inquiry after another (all procedurally and illegally conducted) is that the Supplemental Figure was not substantive to the published Genes & Development paper. This figure made no substantive difference in the conclusions and findings made in the paper. The Supplemental Figure was added at the end at the request of Dr. Satya Prakash who decided to add a figure for western analysis of siRNA depletions even though there was no need for it. If the Supplemental Figure had not been included, the findings and conclusions of the paper would not have changed. Thus, there was no benefit to Dr. Yoon to falsify or create a fraudulent Supplemental Figure.

Indeed, when you go to the NIH Office of Research Integrity ("ORI") home page (www.ori.hhs.gov), you find that cases where research or scientific misconduct are found, the fraud generally involves tens of figures and papers or grants where the scientist is shown to have *intentionally* published papers and/or grants based wholly on falsified and fabricated data, figures and tables. What you do not find is research

misconduct based on carelessness or sloppiness in creating a single figure that was not substantive to the findings and conclusions of the paper.

One last point that was raised by the SIC was the "lack of molecular weight markers in the corrected Fig. S2." For purposes of clarity, the positions of molecular weight markers are shown on the gels that were run and provided to Dr. Niesel and the SIC. Additionally, and maybe most importantly, the journal Genes & Development did not require them and did not ask for them prior to publishing the corrigendum. This is a non-issue and should not have even been raised by the SIC in the inquiry report.

Conclusion

While Dr. Yoon was careless and sloppy in failing to keep proper records of the gels he used to create the original published Supplemental Figure, he did not commit scientific misconduct or fraud. An investigation is not needed to figure this out. There are no additional data, gels, notebooks or other documents to be produced, either on paper or electronically. Dr. Niesel and the SIC have everything and had the opportunity to review all the documents, gels, data and ask Dr. Yoon about them. There is nothing more an investigation will receive or questions it can ask that were not already provided to, and asked by, Dr. Niesel and the SIC. And, after over three (3) years, this whole process needs to end. The last over three (3) years have been a torture to Dr. Yoon that no one should have to suffer at UTMB. His feelings, concerns, considerations, mental well-being have summarily been ignored to pursue a matter that clearly does not rise to the level of scientific misconduct or fraud. Dr. Yoon respectfully requests that the SIC's request to initiate an investigation be denied and this matter closed. Any other result will only continue to unreasonably punish Dr. Yoon for a mistake that, in all honesty, any other scientist at UTMB could have made if faced with the same conditions: of being put under high pressure of working on extensive revisions for two important papers in two prominent journals (Cell and Genes & Development). Dr. Yoon respectfully requests that the SIC's request for an investigation be denied and this matter ended immediately.

EXHIBIT C - Communication and Notes from Complainant

 From:
 Garg, Nisha

 To:
 Subject:

 Fabrication

Date: Tuesday, April 30, 2019 5:46:13 PM

Hi Dr. Garg,

I am leaving UTMB by May 10th 2019, and I need to report some misconduct of my colleague (Dr. Jung Hoon Yoon) in same lab I'm working in. Actually, I have decided my resignation because of the fraud. About two month ago, I noticed that Dr. Yoon and my PIs published a paper, and found out Dr. Yoon fabricated some data in the supplemental figures using my western blot data. I do not know it affects the conclusion of the paper, but I just thought that it just closed the line.

Because He is a quite influential person for making a direction for our research, I lost my confidence on our research anymore. That's the reason I made my mind to leave.

My PIs (Dr Satya Prakash and Louise Prakash) are totally relying on him, and I believed that they do not know the fraud. They just did not check the raw data when they submitted the paper. I've never told them about what I found. I just don't want to be involved in very awkward situation until I leave.

I have the evidence to prove his intentional fabrications in the paper. First of all, I have been only person who generated western blot data over 8 years. Dr. Yoon never did single western blot after I joined the lab. He mislabeled my western blot data for the publication.

I am willing to testify If it is needed for better ethical science.

Because, the severity of this matter, please keep it confidential. I assume that you are not trying to contact my boss until I leave Galveston. Obviously, they will identify me as the whistleblower considering detailed information which hard to be reached, but I need some time until I go back to my home country for a new job. Please let me know what I should do for resolving this. Thank you.

Sincerely yours

Biochemistry and Molecular Biology

University of Texas Medical Branch

301 University Blvd.

Galveston, TX 77555-1061

Response to Scientific Integrity Committee Inquiry Report

By

Dr. Jung 'Hoon Yoon

October 3, 2022

Executive Summary

- 1. The Scientific Integrity Committee ("SIC") has failed to provide any factual support for their request to initiate an investigation.
- 2. Multiple statements made by the SIC in coming to its conclusion are factually incorrect.
- 3. An investigation is also not warranted because Dr. Yoon has produced all the documents in his possession to the SIO and SIC and he has been thoroughly interviewed twice; there is nothing else for an investigation to receive or learn.
- 4. To support a claim for scientific misconduct, the SIC had to show that Dr. Yoon intended to commit fraud, which it has failed to do. Indeed, upon learning of his mistake, Dr. Yoon reran the experiments to produce a new Supplemental Figure under the watchful eyes of Drs. Louise and Satya Prakash and published it in a corrigendum in Genes & Development, where Dr. Yoon owned his mistake by publicly acknowledging it to the public.
- 5. Dr. Yoon has had to deal with a number of inquiries/investigations over more than three years, all of which have violated Dr. Yoon's legal due process rights, as each failed to follow UTMB's mandated procedures and violated federal law. In particular, multiple sections of federal law 42 CFR Section 93.
- 6. An investigation is not warranted as the evidence shows that at worst, Dr. Yoon was careless putting together a figure that was not substantive to the paper's findings and conclusions.

Introduction

This reply is being provided to rebut the SIC inquiry report that requests that an investigation be initiated into an error by Dr. Jung Hoon Yoon (hereinafter, "Dr. Yoon") regarding the preparation and publication of Figure S2 as part of a paper published in Genes & Development issue of March 1, 2019. Dr. Yoon does not believe an investigation is warranted as there is nothing more to learn and nothing learned to date supports a claim of scientific misconduct. To start, Dr. Yoon has produced all of the documents and electronic files in his possession that are relevant to this matter to Dr. Niesel and the SIC. He has also been extensively interviewed by Dr. Niesel and the SIC on those documents and electronic files and the facts of his mistake. It is not clear to Dr. Yoon what exactly an investigation can learn that has not already been identified and determined by Dr. Niesel and the SIC.

Further, in coming to their conclusion that an investigation should be initiated, the SIC has made multiple conclusory and/or factual statements that the SIC fails to support with actual evidence or that are factually inaccurate. Instead, it is pretty clear that the SIC is making statements based on their opinions, not facts. This is highly problematic as the SIC has been charged with making a determination about Dr. Yoon's future employment and reputation and such a determination must be made based on actual facts. It is unreasonable and unfair for the SIC to come to a conclusion because they "think" something may be possibly true. There are no facts to support initiating an investigation and as stated, no new facts will come to light that have not already been made known to and reviewed by Dr. Niesel and the SIC.

Next, the inquiry and an investigation are to determine if Dr. Yoon committed "scientific misconduct." This is not determined based on a "mistake" standard. For scientific misconduct to be found, there must be intentional, knowingly or reckless actions of fabrication, falsification, plagiarism or other actions that materially deviate from those commonly accepted by the academic community. Here, the SIC has failed to show that Dr. Yoon's actions violated any of these factors. Dr. Yoon does not dispute that he made a mistake and that he could be found careless in not keeping adequate records of the gels he used to create the original Supplemental Figure. But nothing he did rose to the level of scientific misconduct. Particularly, nothing has been found by Dr. Niesel or the SIC to suggest his actions were intentional, knowingly undertaken or reckless. Moreover, upon learning of the error, Dr. Yoon immediately reran all the experiments, ran new western blots and produced a new Supplemental Figure under the watchful eyes of Drs. Louise and Satya Prakash that was published as a corrigendum by Genes and Development. In fact, the corrigendum admitted the mistake in writing for all of the journal's readers to see.

Further, this whole process started in September 2019 based on a complaint filed in April 2019. Since that time, Dr. Yoon has had to deal with one failed inquiry attempt after another. Indeed, the original Scientific Integrity Officer ("SIO"), Dr. Nisha Garg violated Dr. Yoon's due process rights, by failing to follow UTMB's mandated procedures and federal law. Particularly multiple violations by Dr. Garg and others at UTMB and in the UT system of sections of 42 CFR Part 93 through not one, not two but three failed inquiry attempts. In fact, Dr. Garg's first attempt, was rubber stamped by UTMB's General Counsel, at the time Carolee King, and former President Raimer, in violation of UTMB's mandated procedures and federal law. Additionally, Dr. Yoon has been informed that the NIH Office of Research Integrity is currently investigating the actions of Dr. Garg related to her violation of federal law in her investigation of Dr. Yoon.

Moreover, even this current attempt at an inquiry that has been conducted under the guidance of Dr. Niesel has also violated Dr. Yoon's due process rights. Under both UTMB's mandated procedures and federal law, an inquiry is to take place sixty (60) days between its start and the issuance of the SIC inquiry report. Dr. Yoon was notified on February 26, 2022 by Dr. Niesel that an inquiry was being initiated. The SIC report was not provided to Dr. Yoon until August 23, 2022, almost 180 days later. This is not even taking into account the fact that Daniel Sharphorn, the University of Texas System General Counsel informed Dr. Yoon on October 15, 2021, about a year ago, that this new inquiry was to be launched following the firing of Dr. Garg as SIO. So, for over three years Dr. Yoon has been dragged through one illegal inquiry after another for what clearly amounts to an honest mistake.

In the end, Dr. Yoon has suffered greatly for over three (3) years since the first of several attempts to conduct a procedurally and legally correct inquiry was initiated, including one whose illegal investigation report presented in January 2020 stated that Dr. Yoon should be fired. His physical health has suffered greatly and the process has also seriously affected his mental health. There is no reason to continue this process. An investigation should not be initiated. The SIC recommendation should be summarily rejected. With regard to punishment for Dr. Yoon's mistake and carelessness, the emotional and physical toll he has suffered during the last over three (3) years is more than sufficient punishment. Indeed, since January 2020, Dr. Yoon has had to wonder if he would be allowed to continue conducting research in the Prakash lab at UTMB, where he has made significant contributions, after the first procedurally and illegal inquiry/investigation told him he should be fired. No other punishment is warranted. Dr. Yoon respectfully requests that the SIC request to initiate an investigation should be rejected and this matter ended summarily.

Failure to Support a Claim of Scientific Misconduct

The first issue that needs to be dealt with is what is "scientific misconduct." What it is not is a mistake or carelessness. More particularly, as defined by the federal code under 42 CFR §93.104, a finding of scientific misconduct requires that:

- (a) "There be a significant departure from accepted practices of the relevant research community; and
- (b) The misconduct be committed intentionally, knowingly, or recklessly; and
- (c) The allegation be proven by a preponderance of the evidence." (emphasis added)

This definition of scientific misconduct is reiterated by the UTMB Policy and Procedure Manual on Integrity in Research ("PPMIR"), where Misconduct/Fraud in research is defined as:

"fabrication, falsification, plagiarism, or other practices that materially deviate from those that are commonly accepted within the academic community for proposing, conducting, or reporting research. It does not include honest errors or honest differences in interpretations or judgments of data." (emphasis added)

As stated by the UTMB PPMIR, honest errors are not misconduct or fraud. Real scientific misconduct or fraud requires an intent to commit the act. To do the bad thing. This is more than making an honest mistake or being careless. Particularly, one as stated by Dr. Niesel during his interview with Dr. Yoon, was a mistake he owned up to when the corrigendum with Genes & Development was filed. As is detailed below, the SIC has failed to show that Dr. Yoon intended to commit misconduct or fraud and

the SIC has failed to meet the standard required to support a claim of scientific misconduct under federal law or the UTMB PPMIR.

The SIC made several statements in its August 23, 2022 memorandum that are factually incorrect. More particularly, the SIC has made claims about statements made by Dr. Yoon during his interview that are not correct. For instance, the SIC states that

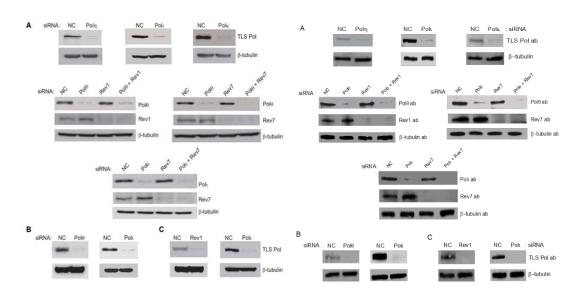
"During that interview, Dr. Yoon acknowledged that the published data was incorrect and was mistakenly included in the manuscript." (3. Background p. 1).

"The respondent stated that he was under high pressure and in a hurry at the time and the incorrect data being utilized was an honest mistake." (IX. Evidence Supporting the SIC's Recommendation to Conduct an Investigation p. 3).

Dr. Yoon did not make the statement that the data was incorrect either during his interview with Dr. Niesel on May 19, 2022 or his interview with the SIC on August 8, 2022. There is no evidence that in putting together the original published Supplemental Figure that Dr. Yoon did not believe he was creating an accurate figure for publication with the correct data. The SIC has failed to produce any evidence to show that the data used to create the original Supplemental Figure was incorrect. Indeed, what is noteworthy is that the Supplemental Figure in the corrigendum appears essentially the same as the original Supplemental Figure.

Original Supplemental Figure 2

Corrigendum Supplemental Figure 2



The Evidence Cited by the SIC Does Not Support a Claim of Scientific Misconduct or Fraud

As evidence supporting a request to initiate an investigation into Dr. Yoon, the SIC states that there were:

"issues with the labeling of images and mismatching of the data for the Figure."

"a lack of details as to the specifics of how the experiment was conducted."

Issues with the respondent being "under high pressure and in a hurry at the time the incorrect data being utilized was an honest mistake."

"a lack of rigor in the approach to assembling this data for this supplementary Figure."

There is nothing in what the SIC claims that supports the initiation of an investigation that would lead a reasonable person to believe that Dr. Yoon undertook actions with the intent to commit scientific misconduct or fraud. Was Dr. Yoon careless in not keeping accurate records of which gels he used to create the original published Supplemental Figure – Yes. He has admitted that. He stated to both Dr. Niesel and the SIC that he was put under a lot of pressure to prepare the original published Supplemental Figure quickly. As a result, he failed to keep adequate records that would have allowed him to go back and identify the gels from which each band set came. That is being sloppy. That is being careless. What that is not is scientific misconduct or fraud. There is nothing that the SIC has stated that even if believed true supports a claim of scientific misconduct or fraud.

And a claim that an investigation would determine if there was falsification of the original data is almost nonsensical. If Dr. Yoon had fabricated the original data, he would not have rerun the experiments to create the Supplemental Figure of the corrigendum. In fact, Drs Louise and Satya Prakash followed Dr. Yoon's work to rerun the experiments and create the data used in the corrigendum Supplemental Figure and both vouch for its accuracy. Moreover, logic says that if the data was fabricated, Dr. Yoon would not have taken the chance of redoing the experiments-because if the results of the corrigendum Supplemental Figure were different, then his guilt would be self-evident. That is not what he did and not what has happened here. He reran all the experiments, he reran all the gels and put together the Supplemental Figure that was published in the corrigendum with an acknowledgement of the mistake made. In fact, in submitting the corrigendum, Dr. Louise Prakash was absolutely clear in her disclosure to Genes & Development about what had happened, when she wrote the following to Genes & Development editor Dr. Laureen Connell that:

"Dr. Jung-Hoon Yoon, the first author of the paper, who had compiled the western blots for the original Supplemental Fig. S2, did not keep a record of western blots used for assembling each segment of Supplemental Fig. S2. Hence, we were unable to confirm that the western blots were assembled correctly. Because of our concern about the accuracy of the data in Supplemental Fig. S2, we asked Dr. Yoon to carry out an entirely new set of experiments so that the accuracy of each step could be unambiguously verified. We have followed this work closely and have gone over the entire set of western blot data carefully; we are confident of its accuracy."

In the corrigendum itself, the authors of the paper published the following statement admitting the mistake (error):

"In Supplemental Fig. S2 in the above article, we have been unable to confirm that the Western blots in panels A-C were assembled correctly. Because of our concerns about the accuracy of the data in the Western blots, we are presenting a new set of verified experiments in the new Supplemental Fig. S2, which can be found in the Revised Supplemental material online. This change in no way affects any of the results or conclusions of this study. The authors apologize for this error"

That is not what someone who commits scientific misconduct or fraud would have done. This is what someone who made a mistake would do to clean up the record. That is what happened here and as Dr. Niesel stated during his interview with Dr. Yoon, Dr. Yoon owned up to his mistake.

Complainant Made False Statements to Dr. Garg

Additionally, there are serious concerns about the veracity and honesty of the complainant Jeseong Park, who was a member of the Prakash lab. In his complaint letter dated April 30 2019, Dr. Park makes several claims that are difficult to reconcile with the truth. These include his claims that:

"I have decided my resignation because of the fraud."

"I lost my confidence on our research anymore. That's the reason I made my mind to leave."

With these statements, it is clear that the complainant Dr. Park led Dr. Nisha Garg, the first SIO who dealt with this matter, and the first to violate the UTMB procedures and federal law, to believe that he had to leave the Prakash's lab due to the actions of Dr. Yoon that he allegedly discovered. He failed to notify Dr. Garg that he was filing his complaint, not upon review of the paper but only after he learned that he was not included as an author of the Genes & Development paper and that he was the third author of a Cell paper that had recently been published, instead of second author that he believed he deserved. Dr. Park blamed Dr. Yoon for these alleged slights as Dr. Park believed that Dr. Yoon did not fight for him to get the authorship Dr. Park believed he deserved. This animosity toward Dr. Yoon festered and manifested in the complaint filed against Dr. Yoon. The irony is that the majority of the gel bands alleged by Dr. Park in his complaint to constitute the ones used by Dr. Yoon in the original Supplemental Figure were in fact not used in that Figure.

Moreover, Dr. Park failed to state that he had been looking for a job for a while prior to filing the complaint with Dr. Garg. Indeed, he had accepted one on April 19, 2019, at InnoPharmamarScreen, almost two weeks *before* filing the complaint. In essence, Dr. Park had decided to leave to go back to South Korea for his own personal professional benefit, not because of some alleged issue with Dr. Yoon related to an alleged fraud. Dr. Park lied to Dr. Garg. Thus, it is not surprising that his claims about the gel bands used were also false, a fraud perpetrated by Dr. Park.

Additional Comments

What appears to have been lost over the last over three (3) years of one inquiry after another (all procedurally and illegally conducted) is that the Supplemental Figure was not substantive to the published Genes & Development paper. This figure made no substantive difference in the conclusions and findings made in the paper. The Supplemental Figure was added at the end at the request of Dr. Satya Prakash who decided to add a figure for western analysis of siRNA depletions even though there was no need for it. If the Supplemental Figure had not been included, the findings and conclusions of the paper would not have changed. Thus, there was no benefit to Dr. Yoon to falsify or create a fraudulent Supplemental Figure.

Indeed, when you go to the NIH Office of Research Integrity ("ORI") home page (www.ori.hhs.gov), you find that cases where research or scientific misconduct are found, the fraud generally involves tens of figures and papers or grants where the scientist is shown to have *intentionally* published papers and/or grants based wholly on falsified and fabricated data, figures and tables. What you do not find is research

misconduct based on carelessness or sloppiness in creating a single figure that was not substantive to the findings and conclusions of the paper.

One last point that was raised by the SIC was the "lack of molecular weight markers in the corrected Fig. S2." For purposes of clarity, the positions of molecular weight markers are shown on the gels that were run and provided to Dr. Niesel and the SIC. Additionally, and maybe most importantly, the journal Genes & Development did not require them and did not ask for them prior to publishing the corrigendum. This is a non-issue and should not have even been raised by the SIC in the inquiry report.

Conclusion

While Dr. Yoon was careless and sloppy in failing to keep proper records of the gels he used to create the original published Supplemental Figure, he did not commit scientific misconduct or fraud. An investigation is not needed to figure this out. There are no additional data, gels, notebooks or other documents to be produced, either on paper or electronically. Dr. Niesel and the SIC have everything and had the opportunity to review all the documents, gels, data and ask Dr. Yoon about them. There is nothing more an investigation will receive or questions it can ask that were not already provided to, and asked by, Dr. Niesel and the SIC. And, after over three (3) years, this whole process needs to end. The last over three (3) years have been a torture to Dr. Yoon that no one should have to suffer at UTMB. His feelings, concerns, considerations, mental well-being have summarily been ignored to pursue a matter that clearly does not rise to the level of scientific misconduct or fraud. Dr. Yoon respectfully requests that the SIC's request to initiate an investigation be denied and this matter closed. Any other result will only continue to unreasonably punish Dr. Yoon for a mistake that, in all honesty, any other scientist at UTMB could have made if faced with the same conditions: of being put under high pressure of working on extensive revisions for two important papers in two prominent journals (Cell and Genes & Development). Dr. Yoon respectfully requests that the SIC's request for an investigation be denied and this matter ended immediately.

From: Yoon, Jung hoon
To: Peter Weinstein

Subject: Fw: UTMB SIO Transition

Date: Tuesday, September 20, 2022 10:01:41 PM

From: Okorodudu, Anthony O. <aookorod@UTMB.EDU>

Sent: Tuesday, September 20, 2022 8:07 AM **To:** Yoon, Jung hoon <juyoon@UTMB.EDU>

Cc: Hebbar, Rohan <rohebbar@UTMB.EDU>; Comvalius-Goddard, Sharon A.

<sacomval@UTMB.EDU>; Niesel, David W. <dniesel@UTMB.EDU>; peter.weinstein@entraltra.com

<peter.weinstein@entraltra.com>

Subject: UTMB SIO Transition

Dear Dr. Yoon,

My name is Dr. Anthony Okorodudu. I am a professor in the Department of Pathology and as you may already know, have been appointed by interim President, Dr. Charles Mouton, as UTMB's Scientific Integrity Officer ("SIO") effective September 1, 2022. Prior to this appointment, I had served three years as a member and chair of our Scientific Integrity Committee.

I am aware that you have a case pending in front of the UTMB *ad hoc* Scientific Integrity Committee ("ad hoc SIC"), so I am emailing you to inform you of my assumption of the SIO role. Please note that any comments you have regarding the contents of the *ad hoc* SIC's inquiry report must be emailed to me by the end of the day on October 7, 2022 at the latest (extension from original deadline set out in UTMB's Policy and Procedure on Integrity in Research). I will forward your comments, if any, to Dr. Mouton.

As with my predecessor, Dr. Niesel, please know that I come to this role unbiased and focused on helping you and the committee navigate this process.

Sincerely,

Anthony O. Okorodudu, Ph.D., MBA
Professor of Pathology
Director, Clinical Chemistry Division & Sample Management
and Client Services
Director, UTMB/TDCJ-CMC Laboratory Services
Department of Pathology (Rm: CSW 7.412QA)
University of Texas Medical Branch
Galveston, TX 77555-0423
Tel: 409 772-3309

Fax: 409 772 9231 or 9224 emaíl: aookorod@utmb.edu

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The information contained in this e-mail message is intended only for the personal and confidential use of the recipient(s) named above. If the reader of this message is not the intended recipient or an agent responsible for delivering it to the intended recipient, you are hereby notified that you have received this document in error and that any review, dissemination, distribution, or copying of this message is strictly prohibited. If you have received this communication in error, please notify us immediately by e-mail, and delete the original message.



Charles P. Mouton, MD, MS, MBA President, ad interim

301 University Blvd. Galveston, Texas 77555-0129 O 409.772.1902 F 409.772.5064

October 7, 2022

Anthony O. Okorodudu, PhD, MBA Scientific Integrity Officer Professor, Pathology, The University of Texas Medical Branch at Galveston

RE: Scientific Integrity Committee Inquiry Report – Jung-Hoon Yoon, PhD, Research Scientist III, Department of Biochemistry and Molecular Biology

Dear Dr. Okorodudu,

I have received the *ad hoc* Scientific Integrity Committee's ("*ad hoc* SIC") inquiry report ("Inquiry Report") regarding an allegation of research misconduct involving Jung-Hoon Yoon, PhD ("Respondent") as well as Respondent's comments to the Inquiry Report. After reviewing the Inquiry Report and Respondent's comments to the Inquiry Report, I have decided to accept the *ad hoc* SIC's recommendation that an investigation is warranted in this case. Please inform the relevant parties and move forward with an investigation in accordance with UTMB's Policy and Procedure Manual on Integrity in Research.

Sincerely,

Charles P. Mouton, MD, MS, MBA

President, ad interim

Executive Provost and Executive Dean

Thomas N. and Gleaves T. James Distinguished Chair

Cc: Carolanda B. Woodgett, JD - VP and Interim Chief Legal Officer

Rohan Hebbar, JD, LLM – Assistant VP, Legal Affairs

Sharon Comvalius-Goddard, Ed.D, MPH – Assoc VP for Research Regulations & Compliance

University of Texas, Medical Branch in Galveston ("UTMB")

Confidential Sensitive

Allegations of Research Misconduct **Respondent: Yoon, Jung-Hoon, PhD**Date of SIC Meeting: December 19, 2019

Report Date: January 2, 2020

1. <u>INVESTIGATION REPORT</u>

1.a. Background and summary of Inquiry

In a message dated May 5, 2019, allegations of research misconduct were raised by a complainant against Yoon, Jung-Hoon, PhD, Research Scientist in the Department of Biochemistry and Molecular Biology (BMB) in the laboratory of Dr. Satya Prakash and Dr. Louise Prakash. The allegations stated possible research misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite 1, N⁶-ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019).

Panel A - top left: blot for TLS Pol in NC/Poln samples is from another blot for a different protein.

Panel A - middle left: Polφ data is from another blot for a different protein in different cells, Rev1 blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Polt data are from a blot for another protein.

Panel B- Western blot for Poli and tubulin for NC/Polo samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data

This manuscript cites support from US PHS funds, specifically NIH grants ES022948 (PI: L Prakash) and GM126087 (PI: L Prakash).

Dr. NJ Garg Scientific Integrity Officer (UTMB) met the complainant in May 2019 and received the material justifying the allegation. The material received from complainant is attached as **Appendix 1.**

Dr. Garg (and Ms. Bricker) met Dr. Yoon (identified as respondents) and lab PIs (Dr. S. Prakash and Dr. L Prakash) on Sept 16 and Sept 17 to present the allegation. Notebooks and computer hard drive were sequestered on September 16. The Scientific Integrity Committee members determined there is sufficient ground to perform investigation.

The Investigation

1.b. Names, titles and CVs for UTMB SIC members involved in Inquiry and Investigation.

The members of the UTMB standing SIC are listed below. The biosketches of the members are available on request.

Dr. Nisha J Garg, PhD MBA (Professor, Microbiology & Immunology, School of Medicine (SOM) and Scientific Integrity Officer)

- Dr. Giulio Tagliatela, PhD (Professor, Neuroscience, SOM and Chair, SIC)
- Dr. David H Walker, PhD (Professor, Pathology, SOM)
- Dr. Lorraine Evangelista, PhD (Professor, School of Nursing)
- Dr. Blake Rasmussen, PhD (Professor, Nutrition and metabolism, School of Health Professions)
- Dr. Rebeca Wong, PhD (Professor, Preventive Medicine and Community Health, SOM)
- Dr. B Monte Pettitt (Professor, Biochemistry & Molecular Biology, SOM)
- Dr. V Suzanne Klimberg (Professor, Surgery, SOM)
- Ms. Carolee A King (JD Senior Vice President & General Counsel, ex officio member)
- Ms. Kimblyn Raschke / Ms. Nancy Bricker (Administrative support, ex officio)

1.c. Names and title of all respondents:

Respondent Yoon, Research Scientist, Biochemistry and Molecular Biology, UTMB Respondent S Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent L Prakash, Professor, Biochemistry and Molecular Biology, UTMB

1.d. Attorneys if relevant: None

1.e. PHS support/ORI jurisdiction.

The following grants funded by NIH were cited in the publication:

<u>Paper</u> <u>Grants</u>

Paper: Genes & Development 33:282-287 (2019) ES022948 and GM126087

2. Investigation process:

Dr. Garg and Ms. Bricker met the respondents on Sept 6-7, 2019 to present the allegation and sequester the relevant notebooks and hard drive.

The respondents kept contact with Dr. Garg through emails and phone calls and provided detailed response on November 18, 2019. The statements received from respondents are attached as **Appendix 2**. Respondents also provided new data (**Appendix 3**) and communications with the journal (**Appendix 4**).

The collected information and data were sent to the members of the SIC investigation committee electronically on 11/19/2019. Members discussed the case electronically and formally met on December 19, 2019.

The presented report was approved by SIC members by January 25, 2020 and the legal counsel on February 6, 2020.

3. Summary:

Respondent Dr. Yoon accepted the responsibility for erroneous presentation of WB images in Figure S2. Respondent maintains that it was an honest error, and he could not identify the original gels that were used to submit Figure S2. Lacking that, all experiments/WB for Figure S2 were repeated, and new data were utilized to assemble new Figure S2 (attached as Appendix 3). Dr. L Prakash has sent the newly generated Figure S2 to the G&D journal (Appendix 4). The journal has published revised version of the Figure S2 as corrigendum.

Scientific Integrity Committee: The person who ran Western blots in the lab has moved to another location. His folders were sequestered and found to be appropriately labeled with all details and needed information. However, the data presented in S2 Figure were found to be cut from images that belonged to data collected with other antibodies. SIC members concurred that erroneous use of western blot images for multiple panels cannot occur by honest error, and recklessness led to falsification and fabrication of multi-panel data presented in Figure S2.

- **4. Recommendations of the SIC**: Members of the SIC recommended the following:
 - 1. SIC members request the Chair of the Department to evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images.
 - 2. Dismissal of Dr. Hoon from UTMB.
 - 3. Notification to the Office of Research Integrity and Federal Funding Agency
- 5. Notice to the respondent of the institutional decision and administrative action. Pending

Submitted by:

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston

O: 409-747-6865, E: nigarg@utmb.edu

University of Texas, Medical Branch in Galveston ("UTMB")

Confidential Sensitive

Allegations of Research Misconduct Respondent: Prakash Louise, PhD

Date of SIC Meeting: December 19, 2019

Report Date: January 2, 2020

1. <u>INVESTIGATION REPORT</u>

1.a. Background and summary of Inquiry

In a message dated May 5, 2019, allegations of research misconduct were raised by a complainant. The allegations stated possible research misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite $1, N^6$ -ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019).

Panel A - top left: blot for TLS Pol in NC/Poln samples is from another blot for a different protein.

Panel A - middle left: Polo data is from another blot for a different protein in different cells, Rev1 blot is mirror imaged, tubulin data are from another experiment.

Panel A - middle right: Rev7 data is from another blot for a different protein and tubulin data are from another experiment.

Panel A - bottom: Poli data are from a blot for another protein.

Panel B- Western blot for Poli and tubulin for NC/Polo samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data

This manuscript cites support from US PHS funds, specifically NIH grants ES022948 and GM126087 (PI: L Prakash).

Though the complainant identified Yoon, Jung-Hoon, PhD, Research Scientist in the Department of Biochemistry and Molecular Biology (BMB) as respondent, the work was funded by NIH grants awarded to Dr. Prakash. Thus, she was also identified as a respondent.

Dr. NJ Garg Scientific Integrity Officer (UTMB) met the complainant in May 2019 and received the material justifying the allegation. The material received from complainant is attached as **Appendix 1.**

Dr. Garg (and Ms. Bricker) met Dr. Yoon, Dr. S. Prakash and Dr. L Prakash (identified as respondents) on Sept 16 and Sept 17 to present the allegation. Notebooks and computer hard drive were sequestered on September 16. The Scientific Integrity Committee members determined there is sufficient ground to perform investigation.

The Investigation

1.b. Names, titles and CVs for UTMB SIC members involved in Inquiry and Investigation.

The members of the UTMB standing SIC are listed below. The biosketches of the members are available on request.

Dr. Nisha J Garg, PhD MBA (Professor, Microbiology & Immunology, School of Medicine (SOM) and Scientific Integrity Officer)

- Dr. Giulio Tagliatela, PhD (Professor, Neuroscience, SOM and Chair, SIC)
- Dr. David H Walker, PhD (Professor, Pathology, SOM)
- Dr. Lorraine Evangelista, PhD (Professor, School of Nursing)
- Dr. Blake Rasmussen, PhD (Professor, Nutrition and metabolism, School of Health Professions)
- Dr. Rebeca Wong, PhD (Professor, Preventive Medicine and Community Health, SOM)
- Dr. B Monte Pettitt (Professor, Biochemistry & Molecular Biology, SOM)
- Dr. V Suzanne Klimberg (Professor, Surgery, SOM)
- Ms. Carolee A King (JD Senior Vice President & General Counsel, ex officio member)
- Ms. Kimblyn Raschke / Ms. Nancy Bricker (Administrative support, ex officio)

1.c. Names and titles of all respondents:

Respondent L Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent Yoon, Research Scientist, Biochemistry and Molecular Biology, UTMB Respondent S Prakash, Professor, Biochemistry and Molecular Biology, UTMB

1.d. Attorneys if relevant: None

1.e. PHS support/ORI jurisdiction.

The following grants funded by NIH were cited in the publication:

<u>Paper</u> <u>Grants</u>

Paper: Genes & Development 33:282-287 (2019) ES022948 and GM126087

2. Investigation process:

Dr. Garg and Ms. Bricker met the respondents on Sept 6-7, 2019 to present the allegation and sequester the relevant notebooks and hard drive.

The respondent L Prakash kept contact with Dr. Garg through emails and phone calls and provided detailed response on November 18, 2019. The statements received from all respondents are attached as **Appendix 2**. Respondent has also provided new data (**Appendix 3**) and communications with the journal (**Appendix 4**).

The collected information and data were sent to the members of the SIC investigation committee electronically on 11/19/2019. Members discussed the case electronically and formally met on December 19, 2019.

The presented report was approved by SIC members by January 25, 2020 and the legal counsel on February 6, 2020.

3. Summary:

Dr. L Prakash (respondent) and other respondents maintain that it was an honest error, that occurred due to mismanagement of data storage. All respondents could not identify the original gels that were used to submit Figure S2. Lacking that, all experiments/WB for Figure S2 were repeated, and new data were utilized to assemble new Figure S2 (attached as Appendix 3). Dr. L Prakash (respondent) has sent the newly generated Figure S2 to the G&D journal (Appendix 4). The journal accepted to publish revised version of the Figure S2 as corrigendum.

Scientific Integrity Committee: The person who ran Western blots in the lab has moved to another location. His folders were sequestered and found to be appropriately labeled with all details and needed information. However, the data presented in S2 Figure were found to be cut from images that belonged to data collected with other antibodies. Dr. Yoon was directly involved in assembling the data for publication and he accepted the responsibility for mis-presentation of data.

SIC members unanimously concluded that falsification and fabrication of data occurred. However, SIC members identified that Dr. L Prakash does not directly guide Dr. Yoon, she did not have direct knowledge of mis-presentation of data, and she was not involved in falsification and fabrication of the data presented in Figure S2.

- **4. Recommendations of the SIC**: Members of the SIC recommended the following:
 - 1. SIC members request the Chair of the Department to evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis. It will be essential that PI is aware of and has confirmed the accuracy of all raw data to be used for future publications.
 - 2. Notification to the Office of Research Integrity and Federal Funding Agency.
- 5. Notice to the respondent of the institutional decision and administrative action. Pending

Submitted by:

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston

O: 409-747-6865, E: nigarg@utmb.edu

University of Texas, Medical Branch in Galveston ("UTMB")

Confidential Sensitive

Allegations of Research Misconduct Respondent: Prakash Satya, PhD

Date of SIC Meeting: December 19, 2019

Report Date: January 2, 2020

1. <u>INVESTIGATION REPORT</u>

1.a. Background and summary of Inquiry

In a message dated May 5, 2019, allegations of research misconduct were raised by a complainant. The allegations stated possible research misconduct in the form of falsification and fabrication of data presented in Supplemental Figure S2 in the following manuscript:

Yoon et al, DNA polymerase theta accomplishes trans-lesion synthesis opposite $1, N^6$ -ethenodeoxyadenosine with a remarkably high fidelity in human cells. Genes & Development 33:282-287 (2019).

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Panel A - bottom: Poli data are from a blot for another protein.

Panel B- Western blot for Poli and tubulin for NC/Polo samples are falsified

Panel C- Western blots for TLS Pol and tubulin in NC/Rev1 samples are falsified from other data

This manuscript cites support from US PHS funds, specifically NIH grants ES022948 and GM126087 (PI: Prakash).

Though the complainant identified Yoon, Jung-Hoon, PhD, Research Scientist in the Department of Biochemistry and Molecular Biology (BMB) as respondent. Dr. Yoon was identified to directly report to Dr. S Prakash. Thus, Dr. S Prakash was also identified as respondent.

Dr. NJ Garg Scientific Integrity Officer (UTMB) met the complainant in May 2019 and received the material justifying the allegation. The material received from complainant is attached as **Appendix 1.**

Dr. Garg (and Ms. Bricker) met Dr. Yoon, Dr. S. Prakash and Dr. L Prakash (identified as respondents) on Sept 16 and Sept 17 to present the allegation. Notebooks and computer hard drive were sequestered on September 16. The Scientific Integrity Committee members determined there is sufficient ground to perform investigation.

The Investigation

1.b. Names, titles and CVs for UTMB SIC members involved in Inquiry and Investigation.

The members of the UTMB standing SIC are listed below. The biosketches of the members are available on request.

Dr. Nisha J Garg, PhD MBA (Professor, Microbiology & Immunology, School of Medicine (SOM) and Scientific Integrity Officer)

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- Dr. David H Walker, PhD (Professor, Pathology, SOM)
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- Dr. V Suzanne Klimberg (Professor, Surgery, SOM)
- Ms. Carolee A King (JD Senior Vice President & General Counsel, ex officio member)
- Ms. Kimblyn Raschke / Ms. Nancy Bricker (Administrative support, ex officio)

1.c. Names and titles of all respondents:

Respondent S Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent L Prakash, Professor, Biochemistry and Molecular Biology, UTMB Respondent Yoon, Research Scientist, Biochemistry and Molecular Biology, UTMB

1.d. Attorneys if relevant: None

1.e. PHS support/ORI jurisdiction.

The following grants funded by NIH were cited in the publication:

<u>Paper</u> <u>Grants</u>

Paper: Genes & Development 33:282-287 (2019) ES022948 and GM126087

2. Investigation process:

Dr. Garg and Ms. Bricker met the respondents on Sept 6-7, 2019 to present the allegation and sequester the relevant notebooks and hard drive.

The respondent L Prakash kept contact with Dr. Garg through emails and phone calls and provided detailed response on November 18, 2019. The statements received from all respondents are attached as **Appendix 2**. Respondent has also provided new data (**Appendix 3**) and communications with the journal (**Appendix 4**).

The collected information and data were sent to the members of the SIC investigation committee electronically on 11/19/2019. Members discussed the case electronically and formally met on December 19, 2019.

The presented report was approved by SIC members by January 25, 2020 and the legal counsel on February 6, 2020.

3. Summary:

Dr. S Prakash (respondent) states, "I believe that the pressure of having to deal with a number of different projects simultaneously and the mistake of having a large number of items on the computer screen open at the same time for constructing the figure put Hoon in a state of deep confusion". Dr. S Prakash (respondent) maintains that it was an honest error of Dr. Yoon.

All respondents could not identify the original gels that were used to submit Figure S2. Lacking that, all experiments/WB for Figure S2 were repeated, and new data were utilized to assemble new Figure S2 (attached as Appendix 3). The newly generated Figure S2 was sent to the G&D journal (Appendix 4). The journal accepted to publish revised version of the Figure S2 as corrigendum.

Scientific Integrity Committee: The person who ran Western blots in the lab has moved to another location. His folders were sequestered and found to be appropriately labeled with all details and needed information. However, the data presented in S2 Figure were found to be cut from images that belonged to data collected with other antibodies. Dr. Yoon was directly involved in assembling the data for publication and he accepted the responsibility for mis-presentation of data. Dr. S Prakash was not identified to have direct knowledge of mis-presentation of data.

SIC members unanimously concluded that falsification and fabrication of data occurred. SIC members considered that a lack of supervision and over-confidence in the capabilities of Dr. Yoon likely resulted in mis-presentation of data. However, SIC members concurred that there is no evidence that suggest that Dr. Prakash had direct knowledge of mis-presentation of data and he was likely not involved in falsification and fabrication of the data presented in Figure S2.

- 4. Recommendations of the SIC: Members of the SIC recommended the following:
 - 1. SIC members request the Chair of the Department to evaluate the lab environment and ensure that a system is implemented in the lab for proper recording of the data and gel images, and evaluation of raw data and monitoring of the lab personnel on a regular basis. It will be essential that PI is aware of and has confirmed the accuracy of all raw data to be used for future publications.
 - 2. Notification to the Office of Research Integrity and Federal Funding Agency.
- 5. Notice to the respondent of the institutional decision and administrative action. Pending

Submitted by:

Nisha Jain Garg, PhD MBA

Scientific Integrity Officer

Professor, Microbiology & Immunology

University of Texas Medical Branch, Galveston

O: 409-747-6865, E: nigarg@utmb.edu

From: Peter Weinstein
To: Peter Weinstein
Subject: FW: please check this

Date: Sunday, September 18, 2022 1:12:00 PM

From: S Prakash < lpandsp@gmail.com>
Sent: Tuesday, August 23, 2022 3:41 PM

To: Peter Weinstein < Peter. Weinstein@entralta.com>

Subject: please check this

Just found this email from jeseong - **From:** Park, Jeseong < <u>iepark@UTMB.EDU</u>>

Sent: Monday, April 22, 2019 2:19 PM

To: Prakash, Louise < logical-align: logical-align: lo

Subject: Resignation

Hi Louise,

I got an job offer from the company in Korea last Friday, and I accepted the offer.

They want me to start the job from the last week of May.

To relocate South Korea, I need to do many things to arrange. Therefore I ask your understanding to terminate my job at UTMB on **May 10th**. I wanted to talk to you in person, but just can't wait until you are in.

Thank you.

Jeseong

Jeseong Park, Ph.D.
Biochemistry and Molecular Biology
University of Texas Medical Branch
301 University Blvd.
Galveston, TX 77555-1061

From: Rodecap, Valerie

To: Prakash, Satya

Cc: Yoon, Jung hoon; Johnson, Robert E.; Prakash, Louise

Subject: RE: Publicity efforts on the Yoon-Prakash manuscript

Date: Monday, July 19, 2021 10:52:28 AM

Actually, Mariano just emailed me that Christopher Smith is the contact because Raul retired.

----Original Message-----From: Rodecap, Valerie

Sent: Monday, July 19, 2021 8:55 AM To: Prakash, Satya <saprakas@UTMB.EDU>

Cc: Yoon, Jung hoon <juyoon@UTMB.EDU>; Johnson, Robert E. <roejohns@utmb.edu>; Garcia-Blanco, Mariano

A. <maragarc@UTMB.EDU>; Prakash, Louise <loprakas@UTMB.EDU>

Subject: RE: Publicity efforts on the Yoon-Prakash manuscript

Good Morning Satya,

Congrats to all of you for this publication!!

Yes, Raul Reyes is our contact to the Marketing & Communication Dept.

Please let me know if you need anything else.

Thanks,

Valerie

----Original Message----

From: Prakash, Satya <saprakas@UTMB.EDU>

Sent: Sunday, July 18, 2021 11:33 PM

To: Rodecap, Valerie <varodeca@UTMB.EDU>

Cc: Yoon, Jung hoon < juyoon@UTMB.EDU>; Johnson, Robert E. < roejohns@utmb.edu>; Garcia-Blanco, Mariano

A. <maragarc@UTMB.EDU>; Prakash, Louise <loprakas@UTMB.EDU>

Subject: FW: Publicity efforts on the Yoon-Prakash manuscript

Importance: High

Hi Valerie,

We're interested in following up on publicity for this upcoming paper of ours. Please let me know who the contact person for this purpose is at UTMB so that I can send that name to Dorothy Oddo in the Editorial Editorial Office of Genes & Development.

Thanks,

Satya

----Original Message-----

From: Oddo, Dorothy <doddo@cshl.edu> Sent: Saturday, July 17, 2021 7:09 PM To: Prakash, Satya <saprakas@UTMB.EDU>

Subject: Publicity efforts on the Yoon-Prakash manuscript

WARNING: This email originated from outside of UTMB's email system. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Prakash,

Congratulations on having your paper, "Implications of inhibition of Rev1 interaction with Y-family DNA polymerases for cisplatin chemotherapy," by Jung-Hoon Yoon, Robert E. Johnson, Louise Prakash, and Satya Prakash, accepted for publication in the September 2021 issue of Genes & Development.

We wanted to get in touch with you regarding potential publicity efforts for your G&D manuscript. We are optimistic that general media outlets &/or other scientific journals – such as Science, Nature, Nature Reviews - might be interested in covering this. To facilitate this, we would like to get in touch with the media affairs contact at your institution to see if/what publicity efforts they have planned for your upcoming paper.

If you could please send me the appropriate contact name and e-mail address for someone at your institution I will look into this.

Thanks very much for all of your help,

Dorothy Oddo

Editorial Office

Genes & Development

Case 4:22-cv-04089 Document 1 Filed on 11/23/22 in TXSD Page 514 of 514

From: Peter Weinstein
To: Peter Weinstein
Subject: FW: please check this

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Sent: Tuesday, August 23, 2022 3:41 PM

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They want me to start the job from the last week of May.

To relocate South Korea, I need to do many things to arrange. Therefore I ask your understanding to terminate my job at UTMB on **May 10th**. I wanted to talk to you in person, but just can't wait until you are in.

Thank you.

Jeseong

Jeseong Park, Ph.D.
Biochemistry and Molecular Biology
University of Texas Medical Branch
301 University Blvd.
Galveston, TX 77555-1061